Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 42

Summary of Changes – December 2017

Effective December 21, 2017

Drug Programs Policy and Strategy Branch
Ontario Public Drug Programs
Ministry of Health and Long-Term Care

Visit Summary of Changes: Formulary Edition 42

Ontario

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New Single Source Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	GENERIC NAME	MFR	DBP
02462850	Erelzi	50 mg/mL	Inj Prefilled SensoReady Pen	ETANERCEPT	SDZ	255.0000
02462869	Erelzi	50 mg/mL	Inj Pref Syr	ETANERCEPT	SDZ	255.0000
02462877	Erelzi	25 mg/ 0.5mL	Inj Pref Syr	ETANERCEPT	SDZ	127.5000

Reason For Use Code and Clinical Criteria

Code 512

For the treatment of rheumatoid arthritis (RA) in patients who have severe active disease (greater than or equal to 5 swollen joints and rheumatoid factor positive and/or, anti-CCP positive, and/or radiographic evidence of rheumatoid arthritis) and have experienced failure, intolerance, or have a contraindication to adequate trials of disease-modifying anti-rheumatic drugs (DMARDs) treatment regimens, such as one of the following combinations of treatments:

A. i) Methotrexate (20mg/week) for at least 3 months, AND
   ii) leflunomide (20mg/day) for at least 3 months, in addition to
   iii) an adequate trial of at least one combination of DMARDs for 3 months; OR
B. i) Methotrexate (20mg/week) for at least 3 months, AND
   ii) leflunomide (20mg/day) in combination with methotrexate for at least 3 months; OR
C. i) Methotrexate (20mg/week), sulfasalazine (2g/day) and hydroxychloroquine (400mg/day) for at least 3 months. (Hydroxychloroquine is based by weight up to 400mg per day.)

Maintenance/Renewal:
After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20 percent reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year.
For renewals beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

New Single Source Products (Continued)

Therapy must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

The recommended dosing regimen is 50 mg per week or 25 mg twice weekly

LU Authorization Period: 1 year

Code 513

For the treatment of ankylosing spondylitis (AS) in patients who have severe active disease confirmed by radiographic evidence (see note below) with:

- Age of disease onset equal to or younger than 50; AND
- Low back pain and stiffness for greater than 3 months that improves with exercise and not relieved by rest; AND
- Failure to respond to or documented intolerance to adequate trials of 2 non-steroidal anti-inflammatory drugs (NSAIDs) for at least 4 weeks each; AND
- Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of greater than or equal to 4 for at least 4 weeks while on standard therapy.

NOTE: Radiographic evidence demonstrating the presence of "SI joint fusion" or "SI joint erosion" on x-ray or CT scan, or MRI demonstrating the presence of "inflammation" or "edema" of the SI joint.

Maintenance/Renewal:
After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 50 percent reduction in BASDAI score or greater than or equal to 2 absolute point reduction in BASDAI score.
For funding beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

The recommended dosing regimen is 50 mg per week or 25 mg twice weekly.

LU Authorization Period: 1 year

New Single Source Products (Continued)

Code 514

For the treatment of polyarticular juvenile idiopathic arthritis (pJIA) in patients who have active disease (greater than or equal to 3 swollen joints and greater than or equal to 5 active joints) despite a trial of optimal doses of subcutaneously administered methotrexate (i.e. 15 mg/m2 per week) for at least 3 months. If the patient is unable to tolerate or has a contraindication to subcutaneous methotrexate, the nature of the intolerance or contraindication should be documented.

Maintenance/Renewal:
After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20 percent reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year.
For funding beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

The recommended dosing regimen for pediatric patients ages 4 to 17 years with active pJIA is 0.8mg/kg per week (up to a maximum of 50 mg per week).

LU Authorization Period: 1 year

New Multi-Source Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02458799	CCP-Anastrozole	1mg	Tab	CCP	1.2729

(Interchangeable with Arimidex)

Reason For Use Code and Clinical Criteria

Code 365

For the treatment of metastatic breast cancer in hormone receptor positive post-menopausal women.

LU Authorization Period: Indefinite

Code 396

As an alternative to tamoxifen for the adjuvant treatment of postmenopausal women with hormone receptor positive breast cancer.

LU Authorization Period: Indefinite

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02348705	Atorvastatin	10mg	Tab	SAI	0.2615
02348713	Atorvastatin	20mg	Tab	SAI	0.3268
02348721	Atorvastatin	40mg	Tab	SAI	0.3513
02348748	Atorvastatin	80mg	Tab	SAI	0.3513

(Interchangeable with Lipitor)

New Multi-Source Products (Continued)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02434652	Ach-Escitalopram	10mg	Tab	ACH	0.4318
02434660	Ach-Escitalopram	20mg	Tab	ACH	0.4597

(Interchangeable with Cipralex)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02463792	Taro-Testosterone Gel	1%	2.5g Foil Packet	TAR	1.6726
02463806	Taro-Testosterone Gel	1%	5.0g Foil Packet	TAR	2.9575

(Interchangeable with Androgel)

Reason For Use Code and Clinical Criteria

Code 397

For male patients with confirmed low morning serum testosterone levels associated with documented, symptomatic hypothalamic, pituitary or testicular disease, or in HIV-infected patients.

Note: Older males with nonspecific symptoms of fatigue, malaise, depression who have a low normal random testosterone level do not satisfy these criteria.

LU Authorization Period: 1 year

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT PRICE
02466988	Apo-Desvenlafaxine	50mg	ER Tab	APX	2.3409
02466996	Apo-Desvenlafaxine	100mg	ER Tab	APX	2.3409

(Interchangeable with Pristiq)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT PRICE
02453738	Teva-Fluticasone	50mcg/Actuation	Nas Sp-120 Dose Pk	TEV	21.9700

(Interchangeable with Flonase)

Transition from the Exceptional Access Program to General Benefit

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02230402	Clopixol	10mg	Tab	VLH	0.4200
02230403	Clopixol	25mg	Tab	VLH	1.0501
02230406	Clopixol Depot	200mg/mL	Inj-1mL Pk	VLH	16.3330

Product Status Change from Facilitated Access HIV/AIDS to General Benefit

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
00886157	Zovirax	200mg/5mL	Oral Susp	GSK	0.2596

Revised Therapeutic Note

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
02443902	Mylan-Emtricitabine/Tenofovir Disoproxil	200mg & 300mg	Tab	MYL

(same Therapeutic Note as Truvada and Teva-Emtricitabine/Tenofovir)

Therapeutic Note

Prescribers should be informed and stay current with a drug's official indications in accordance with Health Canada's approved product monograph.

For the treatment of HIV/AIDS. The prescriber must be approved for the Facilitated Access to HIV/AIDS Drug Products mechanism.

For use as pre-exposure prophylaxis (PrEP) of HIV-1 in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 infection in adults at high risk for infection, in accordance with Health Canada's approved product monograph. Approval for the Facilitated Access to HIV/AIDS Drug Products mechanism is not required.

Manufacturer Name Changes

DIN/NPN	CURRENT BRAND NAME	STRENGTH	DOSAGE FORM	CURRENT MFR	NEW MFR
02237556	Euro-Fer	300mg	Cap	EUR	SDZ
01919342	Luvox	50mg	Tab	SPH	BGP
01919369	Luvox	100mg	Tab	SPH	BGP

Product Brand and Manufacturer Name Changes

DIN/PIN	CURRENT BRAND NAME	CURRENT MFR	NEW BRAND NAME	NEW MFR	DOSAGE FORM
09857293	Breeze 2	BAH	Breeze 2 Blood Glucose Test Strip	ADC	Strip
09857453	Contour Next	BAH	Contour Next Blood Glucose Test Strips	ADC	Strip
09857127	Contour	BAH	Contour Blood Glucose Test Strips	ADC	Strip

Drug Benefit Price (DBP) Changes

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP/ UNIT PRICE
00426849	Apo-Folic	5mg	Tab	APX	0.0404
00755842	Apo-Timol	5mg	Tab	APX	0.2077
00755850	Apo-Timol	10mg	Tab	APX	0.3239
00755869	Apo-Timol	20mg	Tab	APX	0.6304
02246699*	Apo-Naproxen EC	250mg	Tab	APX	0.2835
02380242**	Zelboraf	240mg	Tab	HLR	34.1355
02410702	Zaxine	550mg	Tab	SAL	7.7600

* Off-Formulary Interchangeable (OFI) Product

** Exceptional Access Program Product - effective date Nov 17, 2017

Discontinued Products

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

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
00443840	Depakene	250mg	Cap	ABB
00818658	Hytrin	1mg	Tab	ABB
00818682	Hytrin	2mg	Tab	ABB
00818666	Hytrin	5mg	Tab	ABB
00818674	Hytrin	10mg	Tab	ABB
02237887	Mylan-Acebutolol (Type S)	400mg	Tab	MYL
02231491	Mylan-Azathioprine	50mg	Tab	MYL
02390337	Mylan-Entacapone	200mg	Tab	MYL
02357984	Mylan-Risedronate	35mg	Tab	MYL
02383543	Mylan-Valsartan	160mg	Tab	MYL
02391449	Cipralex MELTZ	10mg	Orally Disintegrating Tab	VLH
02391457	Cipralex MELTZ	20mg	Orally Disintegrating Tab	VLH

Delisted Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
01926411	Orudis	100mg	Sup	AVE
00004758*	Kemadrin	5mg	Tab	BWE
00004561*	Sudafed	6mg/mL	O/L	BWE
00004766*	Sudafed	60mg	Tab	BWE
00647942	Ansaid	50mg	Tab	PFI
00600792	Ansaid	100mg	Tab	PFI
02377454	Fragmin	2500IU/mL	Single Dose-4mL Vial Pk	PFI
02089769	Ogen 1.25	1.5mg	Tab	PFI
02089777	Ogen 2.5	3mg	Tab	PFI
02010933	Provera-Pak	10mg	Tab	PFI
02015951	PMS-Ketoprofen	100mg	Sup	PMS
09857339*	Fluanxol Depot	200mg/10mL	Inj Sol-10mL Pk	VLH
09857337*	Fluanxol Depot	200mg/2mL	Inj Sol-2mL Pk	VLH

* Not-a-Benefit (NAB) Product


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