Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 42

Summary of Changes – February 2016

Effective February 25, 2016

Drug Programs Policy and Strategy Branch

Ontario Public Drug Programs

Ministry of Health and Long-Term Care

Visit Summary of Changes: Edition 42 page

Ontario

Table of Contents

New Single Source Products 3
New Multi-Source Products 7
New Off-Formulary Interchangeable (OFI) Products 11
New Diabetic Testing Agent 12
Drug Benefit Price (DBP) Changes 13
Discontinued Products 14
Delisted Products 15

New Single Source Products

DIN/PIN	PRODUCT NAME, STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02439530	Duaklir Genuair 400mcg & 12mcg Metered Dose Pd Inh-60 Dose Pk	ACLIDINIUM BROMIDE & FORMOTEROL FUMARATE DIHYDRATE	AZC	60.0000

Reason For Use Code and Clinical Criteria

Code 459
For the long-term treatment of patients with moderate to severe chronic obstructive pulmonary disease (COPD-see notes below) who have had an inadequate response to a long-acting bronchodilator (i.e., long-acting beta-2 agonist (LABA), or long-acting muscarinic antagonist (LAMA)).

LU Authorization Period: Indefinite.

NOTE: COPD disease severity is based on spirometry, symptoms and disability (see classification tables below).

Classification

COPD Stages - Symptoms and disability:

Mild: Shortness of breath from COPD when hurrying on the level or walking up a slight hill.
Moderate: Shortness of breath from COPD causing the patient to stop after walking approximately 100m (or after a few minutes) on the level
Severe: Shortness of breath from COPD resulting in the patient being too breathless to leave the house, breathless when dressing or undressing (MRC 5), or the presence of chronic respiratory failure or clinical signs of right heart failure

Classification by impairment of lung function:

COPD stage and spirometry (post bronchodilator) FEV1 predicted:

Mild: Greater than or equal to 80 percent
Moderate: 50 to 79 percent
Severe: 30 to 49 percent
Very severe: Less than 30 percent

New Single Source Products (Cont'd...)

DIN/PIN	PRODUCT NAME, STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02423596	Incruse Ellipta 62.5mcg Blister Pd Inh-30 Dose Pk	UMECLIDINIUM	GSK	50.0000

DIN/PIN	PRODUCT NAME, STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02419475	Inflectra 100mg/Vial Inj Pd-Vial Pk	INFLIXIMAB	HOS	525.0000

Reason For Use Code and Clinical Criteria

Code 468

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:

- 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
- i) Methotrexate (20mg/week) for at least 3 months, and ii) leflunomide in combination with methotrexate for at least 3 months; OR
- 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.

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

The recommended dosing regimen is 3mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of 3mg/kg/dose every 8 weeks up to a maximum of six maintenance doses per year.

LU Authorization Period: 1 year.

New Single Source Products (Cont'd...)

Code 469
For the treatment of ankylosing spondylitis (AS) in patients who have severe active disease (confirmed by radiographic evidence (see notes below) with:

- Age of disease onset less than or equal to 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 physician with expertise in rheumatology.

The recommended dosing regimen is 3 to 5mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of up to 5mg/kg/dose every 6 to 8 weeks.

LU Authorization Period: 1 year.

Code 470
For the treatment of psoriatic arthritis in patients who have severe active disease (greater than or equal to 5 swollen joints and radiographic evidence of psoriatic arthritis) despite: i) treatment with methotrexate (20mg/week) for at least 3 months; and ii) one of leflunomide (20mg/day) or sulfasalazine (1g twice daily) for at least 3 months.
If the patient has documented contraindications or intolerances to methotrexate, then only one of leflunomide (20mg/day) or sulfasalazine (1g twice daily) for at least 3 months is required.

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 have objective evidence of preservation of treatment effect.

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

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

LU Authorization Period: 1 year.

New Single Source Products (Cont'd...)

Code 471

For the treatment of severe (see Note 1 below) 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 (see Note 2 below).

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.

Note 1: Definition of severe plaque psoriasis:

- Body Surface Area (BSA) involvement of at least 10 percent, 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.

Note 2: 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 to 30mg/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 percent reduction in PASI, AND
- at least a 50 percent reduction in BSA involvement, AND
- at least a 5 point reduction in DLQI score

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

LU Authorization Period: 1 year.

New Multi-Source Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02443201	Auro-Alfuzosin	10mg	Prolong-Rel Tab	AUR	0.2601

(Interchangeable with Xatral)

Reason For Use Code and Clinical Criteria

Code 351
For the management of benign prostatic hyperplasia where six weeks of treatment with other formulary alpha blockers (e.g. doxazosin, terazosin, tamsulosin) have been ineffective.

LU Authorization Period: Indefinite.

Code 352
For the management of benign prostatic hyperplasia where other formulary alpha blockers (e.g. doxazosin, terazosin, tamsulosin) have produced intolerable side effects.

LU Authorization Period: Indefinite.

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02426382	Bio-Celecoxib	100mg	Cap	BMP	0.1776
02426390	Bio-Celecoxib	200mg	Cap	BMP	0.3553

(Interchangeable with Celebrex)

Reason For Use Code and Clinical Criteria

Osteoarthritis

Code 316
For patients who have failed an adequate trial of acetaminophen (e.g. acetaminophen 1g QID for several weeks) and have had:

History of a documented, clinically significant ulcer or GI bleed; or

Failure or intolerance to at least three listed NSAIDS.

NOTE: The maximum daily dose of celecoxib which will be reimbursed for the treatment of osteoarthritis is 200mg.

LU Authorization Period: 1 year.

Rheumatoid arthritis

Code 317
For patients who have had:

History of a documented, clinically significant ulcer or GI bleed; or Failure or intolerance to at least three listed NSAIDS.

NOTE: The maximum daily dose of celecoxib which will be reimbursed for the treatment of rheumatoid arthritis is 400mg.

LU Authorization Period: 1 year.

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

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02440180	Taro-Clindamycin/Benzoyl Peroxide Gel	1% & 5%	Gel	TAR	0.6857

(Interchangeable with Clindoxyl)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02407418	Mint-Escitalopram	10mg	Tab	MIN	0.4318
02407434	Mint-Escitalopram	20mg	Tab	MIN	0.4597

(Interchangeable with Cipralex)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02448432	Bio-Fluoxetine	20mg	Cap	BMP	0.4598

(Interchangeable with Prozac)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02445964	Bio-Losartan	25mg	Tab	BMP	0.3147
02445972	Bio-Losartan	50mg	Tab	BMP	0.3147
02445980	Bio-Losartan	100mg	Tab	BMP	0.3147

(Interchangeable with Cozaar)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02447193	Bio-Quetiapine	25mg	Tab	BMP	0.1235
02447207	Bio-Quetiapine	100mg	Tab	BMP	0.3295
02447223	Bio-Quetiapine	200mg	Tab	BMP	0.6617
02447258	Bio-Quetiapine	300mg	Tab	BMP	0.9656

(Interchangeable with Seroquel)

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

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02424339	Jamp-Solifenacin	5mg	Tab	JPC	0.4223
02437988	Ran-Solifenacin	5mg	Tab	RAN	0.4223
02424347	Jamp-Solifenacin	10mg	Tab	JPC	0.4223
02437996	Ran-Solifenacin	10mg	Tab	RAN	0.4223

(Interchangeable with Vesicare)

Reason For Use Code and Clinical Criteria

Code 290
For patients with urinary frequency, urgency or urge incontinence who have:
Failed to respond to behavioral techniques AND an adequate trial of oxybutynin with gradual dose escalation has shown to be either ineffective or resulted in unacceptable side effects.

NOTE: If after a trial of 2 weeks patients continue to experience similar side effects and no greater efficacy than oxybutynin, continued therapy with this more costly agent should be reassessed.
Antimuscarinic agents should be used with caution in the elderly due to potentially serious adverse effects (e.g. confusion, psychosis, acute urinary retention, constipation). Antimuscarinic agents should be avoided in older adults with pre-existing cognitive impairment (e.g. dementia) and those who are already using other drugs with significant anticholinergic effects (e.g. tricyclic antidepressants) in order to avoid a high overall anticholinergic drug burden.

LU Authorization Period: Indefinite.

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02423308	Mint-Tolterodine	1mg	Tab	MIN	0.4910
02299593	Teva-Tolterodine	1mg	Tab	TEV	0.4910
02423316	Mint-Tolterodine	2mg	Tab	MIN	0.4910
02299607	Teva-Tolterodine	2mg	Tab	TEV	0.4910

(Interchangeable with Detrol)

Reason For Use Code and Clinical Criteria

Code 290
For patients with urinary frequency, urgency or urge incontinence who have:
Failed to respond to behavioral techniques AND an adequate trial of oxybutynin with gradual dose escalation has shown to be either ineffective or resulted in unacceptable side effects.

NOTE: If after a trial of 2 weeks patients continue to experience similar side effects and no greater efficacy than oxybutynin, continued therapy with this more costly agent should be reassessed.
Antimuscarinic agents should be used with caution in the elderly due to potentially serious adverse effects (e.g. confusion, psychosis, acute urinary retention, constipation). Antimuscarinic agents should be avoided in older adults with pre-existing cognitive impairment (e.g. dementia) and those who are already using other drugs with significant anticholinergic effects (e.g. tricyclic antidepressants) in order to avoid a high overall anticholinergic drug burden. LU Authorization Period: Indefinite.

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

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02413140	Sandoz Tolterodine LA	2mg	SR Cap	SDZ	0.4911
02412195	Teva-Tolterodine LA	2mg	SR Cap	TEV	0.4911
02413159	Sandoz Tolterodine LA	4mg	SR Cap	SDZ	0.4911
02412209	Teva-Tolterodine LA	4mg	SR Cap	TEV	0.4911

(Interchangeable with Detrol LA)

Reason For Use Code and Clinical Criteria

Code 290
For patients with urinary frequency, urgency or urge incontinence who have:
Failed to respond to behavioral techniques AND an adequate trial of oxybutynin with gradual dose escalation has shown to be either ineffective or resulted in unacceptable side effects.

NOTE: If after a trial of 2 weeks patients continue to experience similar side effects and no greater efficacy than oxybutynin, continued therapy with this more costly agent should be reassessed.
Antimuscarinic agents should be used with caution in the elderly due to potentially serious adverse effects (e.g. confusion, psychosis, acute urinary retention, constipation). Antimuscarinic agents should be avoided in older adults with pre-existing cognitive impairment (e.g. dementia) and those who are already using other drugs with significant anticholinergic effects (e.g. tricyclic antidepressants) in order to avoid a high overall anticholinergic drug burden.

LU Authorization Period: Indefinite.

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02449145	Auro-Betahistine	8mg	Tab	AUR	0.2070
02449153	Auro-Betahistine	16mg	Tab	AUR	0.3557
02449161	Auro-Betahistine	24mg	Tab	AUR	0.4983

(Interchangeable with Serc)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02422875	Auro-Montelukast Chewable Tablet	5mg	Chew Tab	AUR	1.2077

(Interchangeable with Singulair)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02414368	Auro-Sildenafil	25mg	Tab	AUR	8.2894
02414376	Auro-Sildenafil	50mg	Tab	AUR	8.8475
02414384	Auro-Sildenafil	100mg	Tab	AUR	9.2000

(Interchangeable with Viagra)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02439050	Auro-Tramadol/Acetaminophen	37.5mg & 325mg	Tab	AUR	0.6264

(Interchangeable with Tramacet)

New Diabetic Testing Agent

PIN	PRODUCT	MFR	COST / UNIT	AMT MOH PAYS	AMT PATIENT PAYS
09857538	Ideal Life Glucose Test Strip	IDL	0.6800	0.6800	0.0000

Drug Benefit Price (DBP) Changes

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
01968017	Neupogen	300mcg/mL	1mL Vial	AMG	173.1890
09853464	Neupogen	480mcg/1.6mL	1.6mL Vial	AMG	277.1020
02315866	Apo-Alfuzosin	10mg	Prolong-Rel Tab	APX	0.2601
02246691	Apo-Hydroxyquine	200mg	Tab	APX	0.1576
00474517	One-Alpha	0.25mcg	Cap	LEO	0.4963
00474525	One-Alpha	1mcg	Cap	LEO	1.4857
00586668	Fucidin	2%	Cr	LEO	0.7340
00586676	Fucidin	2%	Oint	LEO	0.7340
02404184	Mylan-Tolterodine ER	2mg	SR Cap	MYL	0.4911
02404192	Mylan-Tolterodine ER	4mg	SR Cap	MYL	0.4911
02314282	Novo-Alfuzosin PR	10mg	Prolong-Rel Tab	NOP	0.2601
02304678	Sandoz Alfuzosin	10mg	Prolong-Rel Tab	SDZ	0.2601

Discontinued Products

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

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
09857347	Nutramigen A+	0.68kcal/mL	Liq-945mL Pk	MJN
02246542	Novo-Lovastatin	20mg	Tab	NOP
02246543	Novo-Lovastatin	40mg	Tab	NOP
02239748	Novo-Moclobemide	300mg	Tab	NOP
02242657	Ratio-Cefuroxime	500mg	Tab	RPH
02311283	Ratio-Rivastigmine	1.5mg	Cap	RPH
02311291	Ratio-Rivastigmine	3mg	Cap	RPH
02311305	Ratio-Rivastigmine	4.5mg	Cap	RPH
02311313	Ratio-Rivastigmine	6mg	Cap	RPH

Delisted Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
02306239	Citalopram-Odan	20mg	Tab	ODN
02306247	Citalopram-Odan	40mg	Tab	ODN
02379996	Co Mycophenolate	500mg	Tab	COB
02036282*	Cordarone	200mg	Tab	PFI
02126192	Novo-Clobetasol	0.05%	Oint	NOP
02306026	Novo-Rivastigmine	6mg	Cap	NOP
02177722	PMS-Nizatidine	300mg	Cap	PMS
02391236	PMS-Telmisartan	40mg	Tab	PMS
02275287	Ratio-Azithromycin	250mg	Tab	RPH
02103656	Ratio-Clonazepam	0.5mg	Tab	RPH
97983500	Vital HN		Pd-79g Pk	ABB
02361744	Zenhale	50mcg & 5mcg	Metered Dose Inh-120 Dose Pk	MEK

*Remain on Formulary as Not-a-Benefit to serve as reference product in interchangeable group.


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