

# **Ontario Drug Benefit Formulary/Comparative Drug Index**

**Edition 42**

**Summary of Changes – July 2017**

Effective July 31, 2017

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

**Ministry of Health and Long-Term Care**

# Table of Contents

New Single Source Products .....	3
New Multi-Source Products .....	6
New Off-Formulary Interchangeable (OFI) Product .....	7
New Diabetic Testing Agent.....	8
New Nutrition Product.....	9
Product Status Change from Palliative Care Facilitated Access to Limited Use .....	10
Changes to Reason For Use Content.....	11
Drug Benefit Price (DBP) Changes.....	12
Discontinued Products.....	13
Delisted Products.....	14

# New Single Source Products

DIN/PIN	PRODUCT NAME,STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02455323	Brenzys 50mg/mL Inj Sol-Pref Syr	ETANERCEPT	SAM	269.0000
02455331	Brenzys 50mg/mL Sol- Pref AutoInj	ETANERCEPT	SAM	269.0000

## Reason For Use Code and Clinical Criteria

### Code 498

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 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 50mg per week.

LU Authorization Period: 1 year

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

### Code 499

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 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.

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

The recommended dosing regimen is 50mg per week.

LU Authorization Period: 1 year

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

<b>DIN/PIN</b>	<b>PRODUCT NAME,STRENGTH &amp; DOSAGE FORM</b>	<b>GENERIC NAME</b>	<b>MFR</b>	<b>DBP</b>
02449935	Xigduo 5mg & 850mg Tab	DAPAGLIFLOZIN & METFORMIN*	AZC	1.3100
02449943	Xigduo 5mg & 1000mg Tab	DAPAGLIFLOZIN & METFORMIN*	AZC	1.3100

\*Dapagliflozin & Metformin is a Chronic-Use Medication

### **Therapeutic Note:**

For the treatment of patients with type 2 diabetes mellitus who are already stabilized on therapy with metformin and dapagliflozin, to replace the individual components of dapagliflozin and metformin for those patients who have inadequate glycemic control on metformin, a contraindication or intolerance to a sulfonylurea, and for whom insulin is not an option.

# New Multi-Source Products

<b>DIN/PIN</b>	<b>BRAND NAME</b>	<b>STRENGTH</b>	<b>DOSAGE FORM</b>	<b>MFR</b>	<b>DBP</b>
02447878	Auro-Irbesartan HCT	150mg &12.5mg	Tab	AUR	0.3024
02447886	Auro-Irbesartan HCT	300mg &12.5mg	Tab	AUR	0.3024
02447894	Auro-Irbesartan HCT	300mg & 25mg	Tab	AUR	0.3004

(Interchangeable with Avalide)

<b>DIN/PIN</b>	<b>BRAND NAME</b>	<b>STRENGTH</b>	<b>DOSAGE FORM</b>	<b>MFR</b>	<b>DBP</b>
02461307	PMS-Olmesartan	20mg	Tab	PMS	0.3019
02461315	PMS-Olmesartan	40mg	Tab	PMS	0.3019

(Interchangeable with Olmetec)

## New Off-Formulary Interchangeable (OFI) Product

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02462559 (Interchangeable with Sporanox)	Mint-Itraconazole	100mg	Cap	MIN	4.2412

# New Diabetic Testing Agent

DIN/PIN	BRAND NAME	DOSAGE FORM	MFR	UNIT COST
09857563	Accu-Chek Guide Test Strips	Strip	RCH	0.7287



# New Nutrition Product

## H. PEDIATRIC FORMULA, OTHERS

<b>BRAND NAME</b>	<b>STRENGTH, DOSAGE FORM, PACKAGE SIZE</b>	<b>PIN/NPN</b>	<b>MFR</b>	<b>COST PER 1000KCAL</b>	<b>COST PER PKG</b>	<b>AMOUNT MOHLTC PAYS</b>	<b>AMOUNT PATIENT PAYS</b>
Peptamen Junior 1.5	1.5Kcal/mL, Liq - 250mL Tetra Pk	09857562	NES	28.4700	10.6799	10.6799	0.0000

# Product Status Change from Palliative Care Facilitated Access to Limited Use

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP/mL
02242810**	Scopolamine Hydrobromide Injection	0.4mg/mL	Inj Sol (Preservative Free)	OMG	5.1000
02242811**	Scopolamine Hydrobromide Injection	0.6mg/mL	Inj Sol (Preservative Free)	OMG	5.4500
02382857**	Glycopyrrolate Injection	0.2mg/mL	Inj Sol (Preservative Free)	OMG	3.9750
02039508	Glycopyrrolate Injection	0.2mg/mL	Inj Sol (Preservative Free)	SDZ	3.9750

## Reason For Use Code and Clinical Criteria

### Code 481

For the management of patients receiving palliative care\*.

LU Authorization Period: 1 Year.

\*Note: The patient must have a progressive life-limiting illness and require this medication for palliative purposes.

\*\*Products currently also listed as Off Formulary Interchangeable will become LU Benefit.

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
09857384*	Scopolamine Hydrobromide Injection	0.4mg/mL	Inj Sol-1mL Pk	OMG
09857385*	Scopolamine Hydrobromide Injection	0.6mg/mL	Inj Sol-1mL Pk	OMG
09857521*	Glycopyrrolate Injection	0.2mg/mL	Inj Sol-2mL Vial Pk	OMG
09857212*	Sandoz Glycopyrrolate	0.2mg/mL	Inj-1mL Amp Pk	SDZ

\*The use of this Palliative Care Facilitated Access (PCFA) Product Identification Number (PIN) is discontinued as this product is transitioned to the Formulary as a Limited Use drug.

# Changes to Reason For Use Content

<b>DIN/PIN</b>	<b>BRAND NAME</b>	<b>STRENGTH</b>	<b>DOSAGE FORM</b>	<b>MFR</b>
02238453	Xeloda	150mg	Tab	HLR
02426757	Ach-Capecitabine	150mg	Tab	ACH
02421917	Sandoz Capecitabine	150mg	Tab	SDZ
02400022	Teva-Capecitabine	150mg	Tab	TEV
02238454	Xeloda	500mg	Tab	HLR
02426765	Ach-Capecitabine	500mg	Tab	ACH
02421925	Sandoz Capecitabine	500mg	Tab	SDZ
02400030	Teva-Capecitabine	500mg	Tab	TEV

## **Updated Reason For Use Codes**

### **Code 474**

As part of the CAPOX (XELOX) regimen for the treatment of adjuvant stage III and high risk stage II colorectal, small bowel or appendiceal adenocarcinomas.

LU Authorization Period: Indefinite.

# Drug Benefit Price (DBP) Changes

<b>DIN/PIN</b>	<b>BRAND NAME</b>	<b>STRENGTH</b>	<b>DOSAGE FORM</b>	<b>MFR</b>	<b>DBP/Unit Cost</b>
02246084*	Apo-Ipravent	0.06%	Nasal Spray	APX	1.7387
02245664*	Trimebutine	200mg	Tab	AAP	0.6275
02091887	Rifadin	150mg	Cap	SAV	0.6765
02092808	Rifadin	300mg	Cap	SAV	1.0649
02065819	Sabril	500mg	Tab	OVA	0.9566

\*Off-Formulary Interchangeable Product

# Discontinued Products

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

<b>DIN/PIN</b>	<b>BRAND NAME</b>	<b>STRENGTH</b>	<b>DOSAGE FORM</b>	<b>MFR</b>
02285835	Gd-Gabapentin	400mg	Cap	GEM
00000841	Isopto Carpine	1%	Oph Sol	ALC
02147793	Klean-Prep		Pd-1 Kit	RIV
02239746	Novo-Moclobemide	100mg	Tab	NOP
02239747	Novo-Moclobemide	150mg	Tab	NOP
02240868	Novo-Nabumetone	750mg	Tab	NOP
02287692	Ratio-Ramipril Cap	1.25mg	Cap	RPH
09857479*	Midazolam Injection SDZ (Preservative-Free)	5mg/mL	Inj-1mL Pk	SDZ

\*Palliative Care Facilitated Access PIN

# Delisted Products

<b>DIN/PIN</b>	<b>BRAND NAME</b>	<b>STRENGTH</b>	<b>DOSAGE FORM</b>	<b>MFR</b>
09857518	Apo-Travoprost Z	0.004%	Oph Sol-2.5mL Pk	APX
02415739	Apo-Travoprost Z	0.004%	Oph Sol-5mL Pk	APX
02287730	Novo-Desmopressin	0.1mg	Tab	NOP
02287749	Novo-Desmopressin	0.2mg	Tab	NOP
02231184	Novo-Indapamide	2.5mg	Tab	NOP
02361418	Mylan-Anastrozole	1mg	Tab	MYL
02374897	Mylan-Candesartan HCTZ	16mg & 12.5mg	Tab	MYL
02241883	Mylan-Carbamazepine CR	400mg	LA Tab	MYL
02356058	Mylan-Finasteride	5mg	Tab	MYL
02392631*	Mylan-Finasteride HG	1mg	Tab	MYL
02319225	Mylan-Leflunomide	10mg	Tab	MYL
02319233	Mylan-Leflunomide	20mg	Tab	MYL
02088428	Mylan-Tamoxifen	10mg	Tab	MYL
02089858	Mylan-Tamoxifen	20mg	Tab	MYL
02298570	Mylan-Tamsulosin	0.4mg	Cap	MYL
02244462	Mylan-Warfarin	1mg	Tab	MYL
02244463	Mylan-Warfarin	2mg	Tab	MYL
02244464	Mylan-Warfarin	2.5mg	Tab	MYL
02287498	Mylan-Warfarin	3mg	Tab	MYL
02244465	Mylan-Warfarin	4mg	Tab	MYL
02244466	Mylan-Warfarin	5mg	Tab	MYL
02287501*	Mylan-Warfarin	6mg	Tab	MYL
02244467	Mylan-Warfarin	10mg	Tab	MYL
02231184	Novo-Indapamide	2.5mg	Tab	NOP
02277344	Ratio-Trazodone	50mg	Tab	RPH
02277352	Ratio-Trazodone	100mg	Tab	RPH
02277360	Ratio-Trazodone	150mg	Tab	RPH

\*Off-Formulary Interchangeable Product

