

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – September 2020
Effective September 30, 2020

Drug Programs Policy and Strategy Branch
Drugs and Devices Division
Ministry of Health

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Table of Contents

New Single Source Products.....	3
New Multi-Source Products.....	6
New Off-Formulary Interchangeable (OFI) Products.....	9
Transition from Off-Formulary Interchangeable (OFI) Products to General Benefit	10
Addition of Reason For Use Code.....	11
Temporary Benefits.....	15
Drug Benefit Price (DBP) Changes	16
Discontinued Products	17
Delisted Products	18

New Single Source Products

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02485877	Envarsus PA	0.75mg	ER Tab	TACROLIMUS	EVL	2.0406
02485885	Envarsus PA	1mg	ER Tab	TACROLIMUS	EVL	2.5575
02485893	Envarsus PA	4mg	ER Tab	TACROLIMUS	EVL	10.2300

Reason For Use Code and Clinical Criteria

Code 590

For the prophylaxis of organ rejection in allogenic kidney or liver transplant adult patients in combination with other immunosuppressants.

LU Authorization Period: Indefinite

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02483459	Stramucin	2% w/w	Cr	MUPIROCIN CALCIUM	GLP	1.3000/g

New Single Source Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02480786	Xeljanz	10mg	Tab	TOFACITINIB CITRATE	PFI	42.3436

Xeljanz 5mg Tab (DIN 02423898) will have the same LU Code 589 and criteria added as with the 10mg strength.

Reason For Use Code and Clinical Criteria

Code 589

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)

New Single Source Products (Continued)

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

The recommended dosing regimen for induction is 10mg twice daily for at least 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 Xeljanz or be off corticosteroids after the first year of treatment.

The recommended dosing regimen is 5mg twice daily.

Depending on therapeutic response; 10mg twice daily may also be used for maintenance in some patients. However, the lowest effective dose possible should be used for maintenance therapy to minimize adverse effects.

LU Authorization Period: 1 year

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02493373	Toujeo DoubleSTAR	300U/mL	Inj Sol-3mL Pref Pen	INSULIN GLARGINE	SAC	52.8666/ Pref Pen

New Multi-Source Products

Where applicable, please consult the respective brand reference product's drug profile on the ODB e-Formulary for the details of the Limited Use (LU) code and criteria, and/or any associated Therapeutic Notes (TN).

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02476517	NRA-Atorvastatin	10mg	Tab	NRA	0.1743
02476525	NRA-Atorvastatin	20mg	Tab	NRA	0.2179
02476533	NRA-Atorvastatin	40mg	Tab	NRA	0.2342
02476541	NRA-Atorvastatin	80mg	Tab	NRA	0.2342

(Interchangeable with Lipitor – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02486172	NRA-Ramipril	2.5mg	Cap	NRA	0.0817
02486180	NRA-Ramipril	5mg	Cap	NRA	0.0817
02486199	NRA-Ramipril	10mg	Cap	NRA	0.1034

(Interchangeable with Altace – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02477483	NRA-Rosuvastatin	5mg	Tab	NRA	0.1284
02477491	NRA-Rosuvastatin	10mg	Tab	NRA	0.1354
02477505	NRA-Rosuvastatin	20mg	Tab	NRA	0.1692

(Interchangeable with Crestor – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02388944	Telmisartan	40mg	Tab	SAI	0.2161
02388952	Telmisartan	80mg	Tab	SAI	0.2161

(Interchangeable with Micardis – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02395355	Telmisartan/HCTZ	80mg & 12.5mg	Tab	SAI	0.2098
02395363	Telmisartan/HCTZ	80mg & 25mg	Tab	SAI	0.2098

(Interchangeable with Micardis Plus – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02366959	Valsartan	80mg	Tab	SAI	0.2159
02366967	Valsartan	160mg	Tab	SAI	0.2159
02366975	Valsartan	320mg	Tab	SAI	0.2098

(Interchangeable with Diovan – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02388960	Losartan HCT	50mg & 12.5mg	Tab	SIV	0.3147
02388979	Losartan HCT	100mg & 12.5mg	Tab	SIV	0.3082

(Interchangeable with Hyzaar – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02388987	Losartan HCT	100mg & 25mg	Tab	SIV	0.3147

(Interchangeable with Hyzaar DS – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02493780	Acarbose Tablets	50mg	Tab	STR	0.1348
02493799	Acarbose Tablets	100mg	Tab	STR	0.1866

(Interchangeable with Glucobay – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02489635	Dorzolamide and Timolol Eye Drops BP	20mg/mL & 5mg/mL	Oph Sol (With Preservative)	TCI	2.0951/mL

(Interchangeable with Cosopt – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02489368	Latanoprost and Timolol Ophthalmic Solution	50mcg/mL & 5mg/mL	Oph Sol-2.5mL Pk (With Preservative)	TCI	11.0670

(Interchangeable with Xalacom – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02489570	Latanoprost Ophthalmic Solution	50mcg/mL	Oph Sol-2.5mL Pk (With Preservative)	TCI	9.5830

(Interchangeable with Xalatan – LU)

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02494337	Teva-Liothyronine	5mcg	Tab	TEV	1.1587
02494345	Teva-Liothyronine	25mcg	Tab	TEV	1.2595

(Interchangeable with Cytomel)

Transition from Off-Formulary Interchangeable (OFI) Products to General Benefit

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02248624	Faslodex	50mg/mL	Inj Sol	AZC	116.5790/mL
02483610	Fulvestrant Injection	50mg/mL	Inj Sol	SDZ	58.2895/mL
02460130	Teva-Fulvestrant Injection	50mg/mL	Inj Sol	TEV	58.2895/mL

Addition of Reason For Use Code

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02478382	Truxima	100mg/10mL	Inj Sol-10mL Vial Pk	CEH
02478390	Truxima	500mg/50mL	Inj Sol-50mL Vial Pk	CEH

Reason For Use Code and Clinical Criteria

Code 587

Rituximab is used in combination with glucocorticoids for the induction of remission in patients with severely active Granulomatosis with Polyangiitis [(GPA), also known as Wegener's Granulomatosis (WG)] OR microscopic polyangiitis (MPA), for Patients who meet all of the following criteria:

1. The patient must have severe active disease that is life- or organ-threatening as supported by laboratory and/or imaging reports.
AND
2. There is a positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic autoantibodies) or myeloperoxidase-ANCA.
AND
3. Cyclophosphamide cannot be used by the Patient for ONE of the following reasons:
 - a. The patient has failed a minimum of six IV pulses of cyclophosphamide; OR
 - b. The patient has failed three months of oral cyclophosphamide therapy; OR
 - c. The patient has a severe intolerance or an allergy to cyclophosphamide; OR
 - d. Cyclophosphamide is contraindicated; OR
 - e. The patient has received a cumulative lifetime dose of at least 25g of cyclophosphamide; OR
 - f. The patient wishes to preserve ovarian/testicular function for fertility.
4. The request is from a prescriber experienced in the diagnosis and management of GPA, MPA, and vasculitis.

Exclusion criteria:

The patient should not have received a course of rituximab in the prior 6 months.

The recommended dosing regimen for the initial treatment would be a once weekly infusion dosed at 375 milligrams per square metre x 4 weeks.

Addition of Reason For Use Code (Continued)

Case-by-case considerations for patients not meeting the LU criteria may be considered through the Exceptional Access Program.

LU Authorization Period: 1 month (1 treatment course)

Code 588

Rituximab (Truxima) treatment will be used for Patients with severely active Granulomatosis with Polyangiitis [(GPA), also known as Wegener's Granulomatosis (WG)] OR microscopic polyangiitis (MPA) who have achieved disease remission.

Patient must meet all of the following criteria:

1. The Patient must have severe active disease that is life- or organ-threatening as supported by laboratory and/or imaging reports.
2. There is a positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic autoantibodies) or myeloperoxidase-ANCA. A copy of the laboratory report must be provided.
3. Stabilization of the condition with induction doses of cyclophosphamide (injectable or oral doses are acceptable) and a glucocorticoid as combination over 4 to 6 months until disease remission prior to initiation of rituximab.
4. The request is from a prescriber experienced in the diagnosis and management of GPA, MPA, and vasculitis.

Exclusion criteria:

The Patient should not have received a dose of rituximab in the prior 6 months. Doses of rituximab administered at intervals more frequently than every 6 months are not funded.

The recommended dosing regimen: A fixed dose regimen of rituximab of 500mg IV every 6 months.

Case-by-case considerations for Patients not meeting the LU criteria may be considered through the Exceptional Access Program.

LU Authorization Period: 1 year

Addition of Reason For Use Code (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02462877	Erelzi	25mg/0.5mL	Inj Sol-0.5mL Pref Syr Pk	SDZ
02462850	Erelzi	50mg/mL	Inj Sol-1mL Prefilled SensoReady Pen Pk	SDZ
02462869	Erelzi	50mg/mL	Inj Sol-1mL Pref Syr Pk	SDZ

Reason For Use Code and Clinical Criteria

Code 591

For the treatment of severe* plaque psoriasis in patients 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.

Addition of Reason For Use Code (Continued)

** 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

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 Erelzi (Etanercept):

The recommended dose is 50mg subcutaneous twice weekly for 12 weeks followed by maintenance therapy at 25-50mg subcutaneous once weekly as approved by Health Canada. If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended and the physician should consider switching to an alternative biologic agent.

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

LU Authorization Period: 1 year

Temporary Benefits

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
09858127	Sublocade	100mg/0.5mL	Inj Sol- 0.5mL Pref Syr	BUPRENORPHINE	IND	550.0000/Pref Syr
09858128	Sublocade	300mg/1.5mL	Inj Sol- 1.5mL Pref Syr	BUPRENORPHINE	IND	550.0000/Pref Syr

Clinical Criteria:

For the management of moderate to severe opioid use disorder as a part of a complete treatment plan that includes counselling and psychosocial support in adult patients who meet the following criteria:

- The patient has been induced and is stabilized on an equivalent of 8mg to 24mg per day of transmucosal buprenorphine for a minimum of seven days; AND
- The patient is under the care of a health care provider with experience in the diagnosis and management of opioid use disorder; AND
- Each dose is administered subcutaneously in the abdominal region by a certified healthcare provider who has received instruction and training.

Recommended dose: 300mg/month for two months, followed by a maintenance dose of 100mg/month. Maintenance dose may be increased to 300mg/month only if patient does not demonstrate satisfactory clinical response.

NOTE: In clinical trials, the 300mg/month maintenance dose did not provide additional efficacy as compared to the 100mg/month dose and was associated with a higher incidence of adverse events and study discontinuations. A minimum of 26 days is required between consecutive doses.

Drug Benefit Price (DBP) Changes

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
00335134	Perphenazine	2mg	Tab	AAP	0.0668
00335126	Perphenazine	4mg	Tab	AAP	0.0808
00335118	Perphenazine	8mg	Tab	AAP	0.0888
00335096	Perphenazine	16mg	Tab	AAP	0.1359
02083523	Bezalip	400mg	SR Tab	AGP	2.4443
02070847	Soriatane	10mg	Cap	AGP	2.7227
02070863	Soriatane	25mg	Cap	AGP	4.7817
02478382	Truxima	100mg/10mL	Inj Sol-10mL Vial Pk	CEH	297.0000
02478390	Truxima	500mg/50mL	Inj Sol-50mL Vial Pk	CEH	1485.0000
02494078	Mar-Acarbose	50mg	Tab	MAR	0.1348
02494086	Mar-Acarbose	100mg	Tab	MAR	0.1866
02418282	Ultibro Breezhaler	110mcg & 50mcg	Inh Pd-Cap	NOV	2.5830
00568627	Viskazine 10/25	10mg & 25mg	Tab	NOV	1.1557
00568635	Viskazine 10/50	10mg & 50mg	Tab	NOV	1.1557
00716871	Nyaderm	100000U/g	Cr	TAR	0.0960

Discontinued Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02243987	Apo-Amoxi Clav	50mg & 12.5mg/mL	O/L	APX
02321459	Apo-Entacapone	200mg	Tab	APX
02476614	Apo-HYDROmorphone CR	3mg	CR Cap	APX
02476622	Apo-HYDROmorphone CR	4.5mg	CR Cap	APX
02476630	Apo-HYDROmorphone CR	6mg	CR Cap	APX
02476649	Apo-HYDROmorphone CR	9mg	CR Cap	APX
02476657	Apo-HYDROmorphone CR	12mg	CR Cap	APX
02476665	Apo-HYDROmorphone CR	18mg	CR Cap	APX
02476673	Apo-HYDROmorphone CR	24mg	CR Cap	APX
02476681	Apo-HYDROmorphone CR	30mg	CR Cap	APX
02365499	Apo-Naratriptan	1mg	Tab	APX
02264846	Tramacet	37.5mg & 325mg	Tab	JAN
02163934	Tylenol with Codeine No. 2	300mg & 15mg & 15mg	Tab	JAN
02163926	Tylenol with Codeine No. 3	300mg & 15mg & 30mg	Tab	JAN
02349469	Ultram	50mg	Tab	JAN
02247439	Sandoz Bisoprolol	5mg	Tab	SDZ
02247440	Sandoz Bisoprolol	10mg	Tab	SDZ
02410818	Jetrea	2.5mg/mL	Inj Sol-0.2mL Vial Pk (Preservative-Free)	THO

Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02404990	Auro-Anastrozole	1mg	Tab	AUR
02404400	Auro-Letrozole	2.5mg	Tab	AUR
02231675*	Combivent UDV	500mcg/2.5mg/2.5mL	Inh Sol-2.5mL Amp Pk	BOE
02349124	Effient	10mg	Tab	LIL
02229552	Diarr-eze	2mg	Caplet	PMS
02300079	PMS-Enalapril	2.5mg	Tab	PMS
02300087	PMS-Enalapril	5mg	Tab	PMS
02300095	PMS-Enalapril	10mg	Tab	PMS
02300109	PMS-Enalapril	20mg	Tab	PMS
02303949	PMS-Escitalopram	10mg	Tab	PMS
02303965	PMS-Escitalopram	20mg	Tab	PMS
02245480	PMS-Flavoxate	200mg	Tab	PMS
02282348	PMS-Fluconazole	150mg	Cap	PMS
02423944	PMS-Olanzapine ODT	20mg	Rapid Dissolve Tab	PMS
02310260	PMS-Omeprazole DR Tab	20mg	Tab	PMS

Delisted Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02231536	PMS-Pindolol	5mg	Tab	PMS
02231537	PMS-Pindolol	10mg	Tab	PMS
02154463	PMS-Piroxicam	20mg	Sup	PMS
02290111	PMS-Pramipexole	0.25mg	Tab	PMS
02290138	PMS-Pramipexole	0.5mg	Tab	PMS
02290146	PMS-Pramipexole	1mg	Tab	PMS
02290154	PMS-Pramipexole	1.5mg	Tab	PMS
02342146	PMS-Ramipril-HCTZ	5mg & 12.5mg	Tab	PMS
02291789	PMS-Risperidone ODT	1mg	ODT	PMS
02291797	PMS-Risperidone ODT	2mg	ODT	PMS
02370697	PMS-Risperidone ODT	3mg	ODT	PMS
02370700	PMS-Risperidone ODT	4mg	ODT	PMS
02312999	PMS-Valsartan	40mg	Tab	PMS
02313006	PMS-Valsartan	80mg	Tab	PMS
02192284*	Cyclocort	0.1%	Cr	STI

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

