

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – January 2022
Effective January 31, 2022

Drug Programs Policy and Strategy Branch
OHIP, Pharmaceuticals and Devices Division
Ministry of Health

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New Single Source Products

Generic Name: RITUXIMAB

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02513447	Riabni	10mg/mL	Inj Sol-Vial (Preservative-Free)	AMG	29.7000/mL

Reason For Use Code and Clinical Criteria

Code 621

For the treatment of adult patients with severe active rheumatoid arthritis (RA) (greater than or equal to 5 swollen joints and rheumatoid factor positive and/or anti-CCP positive, and radiographic evidence of rheumatoid arthritis) who meet ALL the following criteria:

1. Patient has experienced failure to respond, documented intolerance, or contraindication to optimal use of one of the following disease modifying, anti-rheumatic (DMARD) regimens:
 - 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.)
2. Patient has experienced failure to respond, documented intolerance, or contraindication to an adequate trial of at least ONE anti-TNF agent (e.g., adalimumab, etanercept, infliximab, golimumab, certolizumab pegol).
3. Patient is not using rituximab in a maintenance setting.
4. Patient is not using a treatment course of rituximab earlier than 6 months after the completion of a prior course of rituximab.

New Single Source Products (Continued)

5. Rituximab is not used in combination with another biologic to treat the patient's RA.
6. Treatment must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

One course of treatment is 1000mg followed two weeks later by the second 1000mg dose.

LU Authorization Period: 3 months

Code 622

For the re-treatment of patients with severe active rheumatoid arthritis (RA) (greater than or equal to 5 swollen joints, and rheumatoid factor positive and/or anti-CCP positive, and radiographic evidence of rheumatoid arthritis) who meet ALL the following criteria:

1. Patient has met the initiation criteria for rituximab in accordance with RFU 621;
2. Patient has experienced loss of effect after having responded to the prior treatment course of rituximab (Response is defined as a 20% reduction in the swollen joint count compared to the joint count prior to the first, pre-treatment course evaluated at 3 to 4 months following the administered course AND improvement in 2 swollen joints); AND
3. Patient is not using rituximab in a maintenance setting; AND
4. Patient is not using a treatment course of rituximab earlier than 6 months after the completion of a prior course of rituximab; AND
5. Rituximab is not used in combination with another biologic to treat the patient's RA.
6. Treatment must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

One course of re-treatment is 1000mg followed two weeks later by the second 1000mg dose.

LU Authorization Period: 3 months

New Single Source Products (Continued)

Code 623

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.

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)

New Single Source Products (Continued)

Code 624

Rituximab (Riabni) 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

New Single Source Products (Continued)

Generic Name: HALOBETASOL PROPIONATE & TAZAROTENE

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02499967	Duobrii	0.01% & 0.045%	Lot	BHC	2.0000/g

Generic Name: GLUCAGON

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02492415	Baqsimi	3mg	Nas Pd Device	LIL	131.6000/Device

Reason For Use Code and Clinical Criteria

Code 625

For the treatment of severe hypoglycemia (SH) reactions in patients with diabetes mellitus who are receiving insulin therapy and are at high risk for SH, when impaired consciousness precludes oral carbohydrate.

LU Authorization Period: 1 year

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
02473488	AA-Telmisartan-Amlodipine	80mg & 5mg	Tab	AAP	0.5472
02473496	AA-Telmisartan-Amlodipine	80mg & 10mg	Tab	AAP	0.5472

(Interchangeable with Twynsta – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02479907	Accel-Entecavir	0.5mg	Tab	ACC	4.4000

(Interchangeable with Baraclude – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02494051	Apo-Colesevelam	625mg	Tab	APX	0.8896

(Interchangeable with Lodalis – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02442809	Jamp Trazodone	50mg	Tab	JPC	0.0554
02442817	Jamp Trazodone	100mg	Tab	JPC	0.0989

(Interchangeable with Desyrel – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02442825	Jamp Trazodone	150mg	Tab	JPC	0.1453

(Interchangeable with Desyrel Dividose – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02517116	PMSC-Celecoxib	100mg	Cap	PMS	0.1279

(Interchangeable with Celebrex – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02304376	PMS-Desmopressin	0.2mg	Tab	PMS	1.3217

(Interchangeable with DDAVP – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02505576	PRZ-Rosuvastatin	5mg	Tab	PRZ	0.1284
02505584	PRZ-Rosuvastatin	10mg	Tab	PRZ	0.1354
02505592	PRZ-Rosuvastatin	20mg	Tab	PRZ	0.1692
02505606	PRZ-Rosuvastatin	40mg	Tab	PRZ	0.1990

(Interchangeable with Crestor – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02515377	Brimonidine Tartrate Ophthalmic Solution	0.2% w/v	Oph Sol (With Preservative)	TCl	1.1550/mL

(Interchangeable with Alphagan – LU)

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02519194	Tranexamic Acid	500mg	Tab	JPC	0.8071

(Interchangeable with Cyklokapron)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02505150	PRZ-Sildenafil	25mg	Tab	PRZ	8.2894
02505169	PRZ-Sildenafil	50mg	Tab	PRZ	8.8475

(Interchangeable with Viagra)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02517205	Sandoz Adapalene/Benzoyl Peroxide	0.3% w/w & 2.5% w/w	Top Gel	SDZ	2.1576/g

(Interchangeable with TactuPump Forte)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02437104	Cefazolin for Injection	500mg/Vial	Inj Pd-Vial Pk (Preservative-Free)	STE	4.0000/Vial
02437112	Cefazolin for Injection	1g/Vial	Inj Pd-Vial Pk (Preservative-Free)	STE	6.0000/Vial
02437120	Cefazolin for Injection	10g/Vial	Inj Pd-Vial Pk (Preservative-Free)	STE	56.0000/Vial

(Interchangeable with Cefazolin for Injection)

Transition from Exceptional Access Program to General Benefit

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02287420	Exjade	125mg	Tab for Susp	NOV	11.0375
02461544	Apo-Deferasirox	125mg	Tab for Susp	APX	5.2408
02464454	Sandoz Deferasirox	125mg	Tab for Susp	SDZ	5.2408
02287439	Exjade	250mg	Tab for Susp	NOV	22.0757
02461552	Apo-Deferasirox	250mg	Tab for Susp	APX	10.4820
02464462	Sandoz Deferasirox	250mg	Tab for Susp	SDZ	10.4820
02287447	Exjade	500mg	Tab for Susp	NOV	44.1507
02461560	Apo-Deferasirox	500mg	Tab for Susp	APX	20.9649
02464470	Sandoz Deferasirox	500mg	Tab for Susp	SDZ	20.9649
02452219	Jadenu	90mg	Tab	NOV	10.8920
02485265	Apo-Deferasirox (Type J)	90mg	Tab	APX	2.6303
02489899	Sandoz Deferasirox (Type J)	90mg	Tab	SDZ	2.6303
02507315	Taro-Deferasirox (Type J)	90mg	Tab	TAR	2.6303
02452227	Jadenu	180mg	Tab	NOV	21.7850
02485273	Apo-Deferasirox (Type J)	180mg	Tab	APX	5.2610
02489902	Sandoz Deferasirox (Type J)	180mg	Tab	SDZ	5.2610
02507323	Taro-Deferasirox (Type J)	180mg	Tab	TAR	5.2610
02452235	Jadenu	360mg	Tab	NOV	43.5730
02485281	Apo-Deferasirox (Type J)	360mg	Tab	APX	10.5228
02489910	Sandoz Deferasirox (Type J)	360mg	Tab	SDZ	10.5228
02507331	Taro-Deferasirox (Type J)	360mg	Tab	TAR	10.5228

Product Brand and Manufacturer Name Changes

DIN/PIN	Current Brand Name	Current Mfr	New Brand Name	New Mfr	Strength	Dosage Form
02284030	Desmopressin	AAP	Apo-Desmopressin	APX	0.1mg	Tab
02284049	Desmopressin	AAP	Apo-Desmopressin	APX	0.2mg	Tab

Drug Benefit Price (DBP) Changes

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
00405337	Diazepam	10mg	Tab	AAP	0.1204
02247732	Concerta	18mg	SR Tab	JAN	2.8410
02250241	Concerta	27mg	SR Tab	JAN	3.2786
02247733	Concerta	36mg	SR Tab	JAN	3.7164
02247734	Concerta	54mg	SR Tab	JAN	4.5914
02243796	Pariet	10mg	Tab	JAN	1.3441
02243797	Pariet	20mg	Tab	JAN	2.6882
02244981	Tracleer	62.5mg	Tab	JAN	71.9800
02244982	Tracleer	125mg	Tab	JAN	71.9800
00556734	Vermox	100mg	Tab	JAN	8.5000
02230893	Topamax	25mg	Tab	JNO	1.9080
02230894	Topamax	100mg	Tab	JNO	3.5860
02230896	Topamax	200mg	Tab	JNO	5.2830
02239907	Topamax Sprinkle	15mg	Sprinkle Cap	JNO	1.8180
02239908	Topamax Sprinkle	25mg	Sprinkle Cap	JNO	1.9030
02506459	Noromby	30mg/0.3mL	Inj Sol-0.3mL Pref Syr (Preservative-Free)	JUN	4.9620
02506467	Noromby	40mg/0.4mL	Inj Sol-0.4mL Pref Syr (Preservative-Free)	JUN	6.6160
02506475	Noromby	60mg/0.6mL	Inj Sol-0.6mL Pref Syr (Preservative-Free)	JUN	9.9240
02506483	Noromby	80mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	JUN	13.2320
02506491	Noromby	100mg/mL	Inj Sol-1mL Pref Syr (Preservative-Free)	JUN	16.5400
02506505	Noromby HP	120mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	JUN	19.8480
02506513	Noromby HP	150mg/mL	Inj Sol-1mL Pref Syr (Preservative-Free)	JUN	24.8100

Drug Benefit Price (DBP) Changes (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02241093	Temodal	5mg	Cap	MEK	8.0340
02241094	Temodal	20mg	Cap	MEK	32.1360
02241095	Temodal	100mg	Cap	MEK	160.6862
02312794	Temodal	140mg	Cap	MEK	224.9623
02241096	Temodal	250mg	Cap	MEK	401.7041
02423308	Mint-Tolterodine	1mg	Tab	MIN	0.4910
02423316	Mint-Tolterodine	2mg	Tab	MIN	0.4910
02243595	Asmanex Twisthaler	200mcg/Metered Dose	Pd Inh-60 Dose Pk	OCI	40.4100
02243596	Asmanex Twisthaler	400mcg/Metered Dose	Pd Inh-30 Dose Pk	OCI	40.4100
09857431	Asmanex Twisthaler	400mcg/Metered Dose	Pd Inh-60 Dose Pk	OCI	80.7900
02182815	Cozaar	25mg	Tab	OCI	1.9344
02182874	Cozaar	50mg	Tab	OCI	1.9343
02182882	Cozaar	100mg	Tab	OCI	1.9343
00323071	Diprosone	0.05%	Cr	OCI	0.2174/g
00417246	Diprosone	0.05%	Lot	OCI	0.2100/g
00344923	Diprosone	0.05%	Oint	OCI	0.2284/g
02245329	Fosamax	70mg	Tab	OCI	12.6250
02276429	Fosavance	70mg & 70mcg	Tab	OCI	5.5335
02314940	Fosavance	70mg & 140mcg	Tab	OCI	5.4250
02230047	Hyzaar	50mg & 12.5mg	Tab	OCI	1.9345
02297841	Hyzaar	100mg & 12.5mg	Tab	OCI	1.8939
02241007	Hyzaar DS	100mg & 25mg	Tab	OCI	1.9345
02240521	Maxalt	10mg	Tab	OCI	20.7800
02240518	Maxalt RPD	5mg	Orally Disintegrating Tab	OCI	20.7800
02240519	Maxalt RPD	10mg	Orally Disintegrating Tab	OCI	20.7800
02010909	Proscar	5mg	Tab	OCI	2.4390
02361752	Zenhale	100mcg & 5mcg	Metered Dose Inh- 120 Dose Pk	OCI	107.6400
02361760	Zenhale	200mcg & 5mcg	Metered Dose Inh- 120 Dose Pk	OCI	130.4300

Drug Benefit Price (DBP) Changes (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
00263818	Cotazym	8000 & 30000 & 30000 USP Units	Cap	ORG	0.2362
00502790	Cotazym ECS 8	8000 & 30000 & 30000 USP Units	Ent Microsph Cap	ORG	0.4263
00821373	Cotazym ECS 20	20000 & 55000 & 55000 USP Units	Ent Microsph Cap	ORG	1.1179
02042487	Marvelon 21	0.15mg & 0.03mg	Tab-21 Pk	ORG	19.4400
02042479	Marvelon 28	0.15mg & 0.03mg	Tab-28 Pk	ORG	19.4400
02170698	PMS-Methotrexate	2.5mg	Tab	PMS	0.5027
02268892	Eligard	45mg	Pd Susp Inj-Pref Syr Kit	SAV	1565.1900
02299593	Teva-Tolterodine	1mg	Tab	TEV	0.4910
02299607	Teva-Tolterodine	2mg	Tab	TEV	0.4910

Discontinued Products

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

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02190915	Losec	20mg	DR Tab	CHE
09857195	Losec	20mg	DR Tab	CHE
00452149	Novamoxin	25mg/mL	O/L	TEV
01934171	Novamoxin (Sugar Reduced)	25mg/mL	O/L	TEV
02326043	Teva-Amitriptyline	10mg	Tab	TEV
02413752	PMS-Methylphenidate ER	54mg	SR Tab	PMS
02306042	PMS-Rivastigmine	3mg	Cap	PMS
02267217	Asacol	800mg	Tab	WAR

Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02369680	Apo-Tolterodine	1mg	Tab	APX
02369699	Apo-Tolterodine	2mg	Tab	APX
02241112	Avandia	2mg	Tab	GSK
02241113	Avandia	4mg	Tab	GSK
02241114	Avandia	8mg	Tab	GSK
00355658	Sinemet	100mg & 10mg	Tab	MFC
00851795	Vasotec	2.5mg	Tab	MFC
02231684	Mylan-Trazodone	100mg	Tab	MYL
02413728	PMS-Methylphenidate ER	18mg	SR Tab	PMS
02396076	Ran-Topiramate	25mg	Tab	RAN

