

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – August 2021

Effective August 31, 2021

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

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New Single Source Products

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02480018	Olumiant	2mg	Tab	BARICITINIB	LIL	50.8997

Reason For Use Code and Clinical Criteria

Code 615

For the treatment of rheumatoid arthritis (RA) in combination with methotrexate 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.)

In patients who demonstrated initial response to treatment (defined as an achievement of an American College of Rheumatology [ACR] improvement criteria of at least 20% [ACR20] at week 12), ongoing maintenance therapy is funded.

New Single Source Products (Continued)

Maintenance/Renewal:

After 12 weeks of treatment, maintenance therapy is funded for patients who achieved an American College of Rheumatology (ACR) improvement criteria of at least 20% (ACR20) and a minimum of improvement in 2 swollen joints by week 12.

For renewals beyond 12 months, 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 2mg administered once daily.

Baricitinib should not be used in combination with other Janus kinase (JAK) inhibitors or other biologic DMARDs to treat the patient's RA.

LU Authorization Period: 1 year

Generic Name: PEGFILGRASTIM

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02506238	Nyvepria	6mg/0.6mL	Inj Sol-0.6mL Pref Syr Pk (Preservative-Free)	PFI	1375.0000/Pref Syr

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
02449838	Ach-Pregabalin	25mg	Cap	ACH	0.1481
02449846	Ach-Pregabalin	50mg	Cap	ACH	0.2324
02449854	Ach-Pregabalin	75mg	Cap	ACH	0.3007
02449870	Ach-Pregabalin	150mg	Cap	ACH	0.4145
02449900	Ach-Pregabalin	300mg	Cap	ACH	0.4145

(Interchangeable with Lyrica – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02452510	Apo-Darifenacin	7.5mg	ER Tab	APX	1.2087
02452529	Apo-Darifenacin	15mg	ER Tab	APX	1.2087

(Interchangeable with Enablex – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02501635	Apo-Quetiapine Fumarate	25mg	Tab	APX	0.0494
02501643	Apo-Quetiapine Fumarate	100mg	Tab	APX	0.1318
02501651	Apo-Quetiapine Fumarate	200mg	Tab	APX	0.2647
02501678	Apo-Quetiapine Fumarate	300mg	Tab	APX	0.3863

(Interchangeable with Seroquel – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02499223	Auro-Indomethacin	50mg	Cap	AUR	0.1234

(Interchangeable with Indocid – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02497557	Jamp Sodium Polystyrene Sulfonate	1g/g	Oral Pd-454g Pk	JPC	29.4175

(Interchangeable with Kayexalate – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02502038	M-Azithromycin	250mg	Tab	MAT	0.9410

(Interchangeable with Zithromax – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02475022	Atorvastatin	10mg	Tab	RIA	0.1743
02475030	Atorvastatin	20mg	Tab	RIA	0.2179
02475049	Atorvastatin	40mg	Tab	RIA	0.2342
02475057	Atorvastatin	80mg	Tab	RIA	0.2342

(Interchangeable with Lipitor – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02475278	Donepezil	5mg	Tab	RIA	0.4586
02475286	Donepezil	10mg	Tab	RIA	0.4586

(Interchangeable with Aricept – LU)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02270889	Riva-Alendronate	70mg	Tab	RIA	2.1014

(Interchangeable with Fosamax – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02247217	Riva-Amiodarone	200mg	Tab	RIA	0.3706

(Interchangeable with Cordarone – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02392259	Riva-Anastrozole	1mg	Tab	RIA	0.9522

(Interchangeable with Arimidex – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02275309	Riva-Azithromycin	250mg	Tab	RIA	0.9410

(Interchangeable with Zithromax – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02303264	Riva-Citalopram	20mg	Tab	RIA	0.1332
02303272	Riva-Citalopram	40mg	Tab	RIA	0.1332

(Interchangeable with Celexa – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02468484	Riva-Clindamycin	300mg	Cap	RIA	0.4434

(Interchangeable with Dalacin C – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02441659	Riva-Dorzolamide/Timolol	20mg/mL & 5mg/mL	Oph Sol (With Preservative)	RIA	2.0951/mL

(Interchangeable with Cosopt – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02455013	Riva-Finasteride	5mg	Tab	RIA	0.4138

(Interchangeable with Proscar – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02341085	Riva-Latanoprost	50mcg/mL	Oph Sol-2.5mL Pk	RIA	9.5830

(Interchangeable with Xalatan – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02398656	Riva-Letrozole	2.5mg	Tab	RIA	1.3780

(Interchangeable with Femara – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02341077	Riva-Risedronate	35mg	Tab	RIA	1.9787

(Interchangeable with Actonel – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02509601	Olmesartan/HCTZ	20mg & 12.5mg	Tab	SAI	0.3019
02509636	Olmesartan/HCTZ	40mg & 12.5mg	Tab	SAI	0.3019
02509628	Olmesartan/HCTZ	40mg & 25mg	Tab	SAI	0.3019

(Interchangeable with Olmetec Plus – GB)

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02449897	Ach-Pregabalin	225mg	Cap	ACH	1.7270

(Interchangeable with Lyrica)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02481030	Auro-Zolmitriptan	2.5mg	Tab	AUR	6.8633

(Interchangeable with Zomig)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02402068	Piperacillin and Tazobactam For Injection	2g & 250mg	Inj Pd-2.25g Vial Pk	AUR	10.1300/Vial
02402076	Piperacillin and Tazobactam For Injection	3g & 375mg	Inj Pd-3.375g Vial Pk	AUR	15.2000/Vial
02402084	Piperacillin and Tazobactam For Injection	4g & 500mg	Inj Pd-4.5g Vial Pk	AUR	20.2700/Vial

(Interchangeable with Tazocin)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02514702	Jamp Pirfenidone	267mg	Tab	JPC	6.7120
02514710	Jamp Pirfenidone	801mg	Tab	JPC	20.1360

(Interchangeable with Esbriet Tab DIN 02464489 & DIN 02464500)

New Off-Formulary Interchangeable (OFI) Products (Continued)



DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02346532	Riva-Clarithromycin	500mg	Tab	RIA	2.2009

(Interchangeable with Biaxin BID)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02452413	Riva-Sildenafil	100mg	Tab	RIA	9.2006

(Interchangeable with Viagra)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02454726	Riva-Tadalafil	5mg	Tab	RIA	3.6471
02454742	Riva-Tadalafil	20mg	Tab	RIA	12.3569

(Interchangeable with Cialis)

Addition of Reason For Use Code

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02498316	Riximyo	10mg/mL	Inj Sol-Vial	SDZ

Reason For Use Code and Clinical Criteria

Code 616

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.

Addition of Reason For Use Code (Continued)

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

The recommended dosing regimen for 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)

Code 617

Rituximab (Riximyo) 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.

Addition of Reason For Use Code (Continued)

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 consideration for patients not meeting the LU criteria may be considered through the Exceptional Access Program.

LU Authorization Period: 1 year

Manufacturer Name Changes

DIN/PIN	Brand Name	Strength	Dosage Form	Current Mfr	New Mfr
02166704	Prometrium	100mg	Cap	MEK	OCI

Product Brand and Manufacturer Name Changes

DIN/PIN	Current Brand Name	Current Mfr	New Brand Name	New Mfr	Strength	Dosage Form
02496119	Accel-Pilocarpine	ACC	M-Pilocarpine	MAT	5mg	Tab

Drug Benefit Price (DBP) Changes

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP/Unit Price
00545015	Acetazolamide	250mg	Tab	AAP	0.1414
02478862	Accel Leflunomide	10mg	Tab	ACC	2.0000
02478870	Accel Leflunomide	20mg	Tab	ACC	2.0000
02478927	Accel-Ondansetron	4mg	Tab	ACC	2.5450
02478935	Accel-Ondansetron	8mg	Tab	ACC	3.8840
02327260	Apo-Gatifloxacin (with preservative)	0.3% w/v	Oph Sol	APX	2.0320
02244726	Apo-Medroxy	2.5mg	Tab	APX	0.1183
02461536	Mint-Indomethacin	50mg	Cap	MIN	0.1234
02473941	Odan-Sodium Polystyrene Sulfonate	1mEq/g	Oral Pd-454g Pk	ODN	29.4175
00755338	Solystat	1mEq/g	Oral Pd-454g Pk	PEN	29.4175
02244790	Sandoz Morphine SR	15mg	SR Tab	SDZ	0.4145
00337439	Teva-Indomethacin	50mg	Cap	TEV	0.1234
02221284	Teva-Medroxyprogesterone	2.5mg	Tab	TEV	0.1183
02302764	Teva-Morphine SR	15mg	SR Tab	TEV	0.4145

Discontinued Products

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

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02260107	Sandoz Anagrelide	0.5mg	Cap	SDZ

Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02280396	Apo-Risperidone	1mg/mL	O/L	APX
00839213	Sandostatin	500mcg/mL	Inj Sol-1mL Amp Pk	NOV
02463520	Taro-Deferasirox	125mg	Tab for Susp	TAR
02463539	Taro-Deferasirox	250mg	Tab for Susp	TAR
02463547	Taro-Deferasirox	500mg	Tab for Susp	TAR
02407957	Teva-Deferasirox	125mg	Tab for Susp	TEV
02407965	Teva-Deferasirox	250mg	Tab for Susp	TEV
02407973	Teva-Deferasirox	500mg	Tab for Susp	TEV

