Ontario

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – April 2022
Effective April 29, 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: INSULIN INJECTION, HUMAN BIOSYNTHETIC

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02466864	Entuzity KwikPen	500U/mL	Inj Sol-Pref Pen 2x3mL Pk	LIL	98.5800/Pk

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
02471671	Auro-Amoxiclav	250mg & 125mg	Tab	AUR	0.2467
02471698	Auro-Amoxiclav	500mg & 125mg	Tab	AUR	0.3778

(Interchangeable with Clavulin – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02471701	Auro-Amoxiclav	875mg & 125mg	Tab	AUR	0.5551

(Interchangeable with Clavulin (BID) – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02478501	Auro-Silodosin	4mg	Cap	AUR	0.4742
02478528	Auro-Silodosin	8mg	Cap	AUR	0.4742

(Interchangeable with Rapaflo – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02462656	Med-Clindamycin	150mg	Cap	GMP	0.2217
02462664	Med-Clindamycin	300mg	Cap	GMP	0.4434

(Interchangeable with Dalacin C – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02361450	Bisacodyl Suppository	10mg	Sup	JPC	0.4206

(Interchangeable with Dulcolax – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02502801	Jamp Lamivudine / Zidovudine	150mg & 300mg	Tab	JPC	2.6103

(Interchangeable with Combivir – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02517701	Jamp Midodrine	2.5mg	Tab	JPC	0.1153
02517728	Jamp Midodrine	5mg	Tab	JPC	0.1921

(Interchangeable with Amatine – LU)

DIN/NPN	Product Name	Strength	Dosage Form	Mfr	DBP
80009595	Jamp-Senna	8.6mg	Tab	JPC	0.0464

(Interchangeable with Senokot – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02519755	M-Metronidazole	500mg	Cap	MAT	0.2739

(Interchangeable with Flagyl – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02519844	Alfuzosin	10mg	ER Tab	SAI	0.2601

(Interchangeable with Xatral – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02400529	Clindamycin	150mg	Cap	SAI	0.2217
02400537	Clindamycin	300mg	Cap	SAI	0.4434

(Interchangeable with Dalacin C – GB)

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New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02467119	Desvenlafaxine	50mg	ER Tab	APX	2.3409
02467127	Desvenlafaxine	100mg	ER Tab	APX	2.3409

(Interchangeable with Pristiq)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02469650	NRA-Tramadol/ACET	37.5mg & 325mg	Tab	NRA	0.6264

(Interchangeable with Tramacet)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02519127	Mometasone	50mcg/Dose	Nas Sp-140 Dose Pk	SAI	21.6900

(Interchangeable with Nasonex)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02292297	Ceftriaxone Sodium For Injection BP	10g/Vial	Inj Pd-1 Vial Pk	SDZ	214.2000

(Interchangeable with Rocephin)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02522306	Taro-Acyclovir	5% w/w	Top Oint	TAR	12.3114/g

(Interchangeable with Zovirax)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02458217	Teva-Desvenlafaxine	50mg	ER Tab	TEV	2.3409
02458225	Teva-Desvenlafaxine	100mg	ER Tab	TEV	2.3409

(Interchangeable with Pristiq)

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Transition from Exceptional Access Program to Limited Use

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02459418	Revlimid	2.5mg	Cap	CEL	329.5000
02507927	Apo-Lenalidomide	2.5mg	Cap	APX	82.3750
02484714	Reddy-Lenalidomide	2.5mg	Cap	DRR	82.3750
02506130	Jamp Lenalidomide	2.5mg	Cap	JPC	82.3750
02493837	Nat-Lenalidomide	2.5mg	Cap	NAT	82.3750
02518562	Sandoz Lenalidomide	2.5mg	Cap	SDZ	82.3750

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02304899	Revlimid	5mg	Cap	CEL	340.0000
02507935	Apo-Lenalidomide	5mg	Cap	APX	85.0000
02483017	Reddy-Lenalidomide	5mg	Cap	DRR	85.0000
02506149	Jamp Lenalidomide	5mg	Cap	JPC	85.0000
02493845	Nat-Lenalidomide	5mg	Cap	NAT	85.0000
02518570	Sandoz Lenalidomide	5mg	Cap	SDZ	85.0000

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02304902	Revlimid	10mg	Cap	CEL	361.0000
02507943	Apo-Lenalidomide	10mg	Cap	APX	90.2500
02483025	Reddy-Lenalidomide	10mg	Cap	DRR	90.2500
02506157	Jamp Lenalidomide	10mg	Cap	JPC	90.2500
02493861	Nat-Lenalidomide	10mg	Cap	NAT	90.2500
02518589	Sandoz Lenalidomide	10mg	Cap	SDZ	90.2500

Transition from Off-Formulary Interchangeable (OFI) to Limited Use (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02317699	Revlimid	15mg	Cap	CEL	382.0000
02507951	Apo-Lenalidomide	15mg	Cap	APX	95.5000
02483033	Reddy-Lenalidomide	15mg	Cap	DRR	95.5000
02506165	Jamp Lenalidomide	15mg	Cap	JPC	95.5000
02493888	Nat-Lenalidomide	15mg	Cap	NAT	95.5000
02518597	Sandoz Lenalidomide	15mg	Cap	SDZ	95.5000

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02440601	Revlimid	20mg	Cap	CEL	403.0000
02507978	Apo-Lenalidomide	20mg	Cap	APX	100.7500
02483041	Reddy-Lenalidomide	20mg	Cap	DRR	100.7500
02506173	Jamp Lenalidomide	20mg	Cap	JPC	100.7500
02493896	Nat-Lenalidomide	20mg	Cap	NAT	100.7500
02518600	Sandoz Lenalidomide	20mg	Cap	SDZ	100.7500

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02317710	Revlimid	25mg	Cap	CEL	424.0000
02507986	Apo-Lenalidomide	25mg	Cap	APX	106.0000
02483068	Reddy-Lenalidomide	25mg	Cap	DRR	106.0000
02506181	Jamp Lenalidomide	25mg	Cap	JPC	106.0000
02493918	Nat-Lenalidomide	25mg	Cap	NAT	106.0000
02518619	Sandoz Lenalidomide	25mg	Cap	SDZ	106.0000

Transition from Off-Formulary Interchangeable (OFI) to Limited Use (Continued)

Reason For Use Code and Clinical Criteria

Code 630

Myelodysplastic Syndrome

Initial criteria:

For the treatment of patients with anemia due to myelodysplastic syndrome (MDS) who meet all of the following clinical criteria:

1. Demonstrated diagnosis of myelodysplastic syndrome (MDS) on bone marrow aspiration
2. Presence of deletion 5q cytogenetic abnormality documented by standard cytogenetic, fluorescence in situ hybridization, or genomic testing
3. International Prognostic Scoring System (IPSS) risk category low or intermediate-1
4. Symptomatic anemia (transfusion dependent or non-transfusion dependent)

LU Authorization Period: 6 months

Renewal criteria:

There is at least a fifty percent (50%) reduction in transfusion requirements and/or evidence of hematologic response.

Renewal Duration: 1 year

Recommended dose: 10mg daily adjusted based on clinical and laboratory findings.

Transition from Off-Formulary Interchangeable (OFI) to Limited Use (Continued)

Note: Pharmacists and prescribers should be informed of a drug product's official indications and recommended dosage as set out in Health Canada's approved product monograph. Some aspects of this criteria may differ from the official indications and recommended dosage as described in the product monographs for lenalidomide or other products that may be used as part of combination therapy with lenalidomide. The Executive Officer's funding of drug products is informed by advice from expert committees that consider evidence regarding the safety, clinical efficacy, and cost-effectiveness of the drug products. Where there is a difference between a product monograph and the LU criteria described above, the LU criteria governs for the purpose of funding under the Ontario Drug Benefit Program.

Code 631

Multiple Myeloma (maintenance treatment following stem cell transplant)

Initial criteria:

For the maintenance treatment of patients with newly diagnosed multiple myeloma, following autologous stem-cell transplantation (ASCT) who have stable disease or better, with no evidence of disease progression.

LU Authorization Period: 1 year

Renewal criteria:

Lenalidomide may be continued until evidence of disease progression or development of unacceptable toxicity requiring discontinuation of lenalidomide

Renewal Duration: 1 year

Recommended Dosage: Initial dose of 10mg daily

Dose adjustments (5-15mg) may be necessary based on individual patient characteristics/ responses.

Transition from Off-Formulary Interchangeable (OFI) to Limited Use (Continued)

Note: Pharmacists and prescribers should be informed of a drug product's official indications and recommended dosage as set out in Health Canada's approved product monograph. Some aspects of this criteria may differ from the official indications and recommended dosage as described in the product monographs for lenalidomide or other products that may be used as part of combination therapy with lenalidomide. The Executive Officer's funding of drug products is informed by advice from expert committees that consider evidence regarding the safety, clinical efficacy, and cost-effectiveness of the drug products. Where there is a difference between a product monograph and the LU criteria described above, the LU criteria governs for the purpose of funding under the Ontario Drug Benefit Program.

Code 632

Multiple Myeloma

Initial criteria:

For the treatment of patients with multiple myeloma who meet ALL the following criteria:

1. Patient is deemed to be lenalidomide sensitive, defined as disease that has not been refractory to a lenalidomide-based regimen, and/or has not experienced progression while on a lenalidomide-based regimen in a treatment or maintenance setting (Note 1); AND
2. Patient has good performance status; AND
3. Lenalidomide is being used in ONE of the following situations:
   a) In a transplant ineligible patient with previously untreated multiple myeloma, as first line therapy within a dual regimen in combination with dexamethasone OR as part of a triplet regimen in combination with bortezomib and dexamethasone (Note 2); OR

Transition from Off-Formulary Interchangeable (OFI) to Limited Use (Continued)

b) In a transplant ineligible patient with relapsed or refractory multiple myeloma as second or third line treatment within a dual regimen in combination with dexamethasone; OR as part of a triplet regimen in combination with dexamethasone and carfilzomib; OR as part of a triplet regimen in combination with dexamethasone and daratumumab (Note 3); OR

c) In a patient with relapsed or refractory multiple myeloma who received a stem-cell transplant as first line treatment and is using a lenalidomide based regimen as second or third line treatment within a dual regimen in combination with dexamethasone; OR as part of a triplet regimen in combination with dexamethasone and carfilzomib; OR as part of a triplet regimen in combination with dexamethasone and daratumumab (Note 3).

Notes:

1. Refractory disease is defined as disease progression within 60 days after stopping treatment or progression on any dose of lenalidomide or bortezomib including while on maintenance therapy or non-responsive disease during therapy (either failure to achieve minimal response or disease progression).

Relapsed / Progressive disease is defined as having one or more of the following:

i. An increase of 25% from lowest response value in serum M-component (absolute increase must be greater than or equal to 0.5g/dL), and/or urine M-component (absolute increase must be greater than or equal to 200mg/24 hours).

ii. An absolute increase of greater than 10mg/dL in the difference between involved and uninvolved FLC levels (if no measurable serum and urine M-protein levels).

iii. Definite development of new bone lesions or soft tissue plasmacytomas or definite increase in the size of existing bone lesions or soft tissue plasmacytomas.

iv. Development of hypercalcemia (corrected serum calcium greater than 11.5mg/dL or 2.5 mmol/L) that can be attributed solely to the plasma cell proliferative disorder.

Transition from Off-Formulary Interchangeable (OFI) to Limited Use (Continued)

2. Patients with multiple myeloma who experience disease progression on a lenalidomide-bortezomib-dexamethasone triplet will not be eligible for further lenalidomide-based or bortezomib-based regimens subsequent to disease progression, in both maintenance or relapsed/refractory multiple myeloma settings.
3. Patients using combination regimens must meet the eligibility requirements for bortezomib, carfilzomib and daratumumab through the New Drug Funding Program (NDFP).
4. Patients using lenalidomide in regimens that are not specified in the LU criteria may apply for case-by-case consideration through the EAP.

LU Authorization Period: 1 year

Renewal criteria:

Lenalidomide may be continued for the treatment of multiple myeloma in those who continue to respond to therapy and have not experienced refractory disease or progressive disease while on the lenalidomide-based regimen.

Renewal Duration: 1 year

Exclusion Criteria:

Patients meeting the following are not eligible for funding:

1. Patients with multiple myeloma who have experienced disease that has been refractory to treatment with a lenalidomide-based treatment.
2. Patients with multiple myeloma who have experienced disease progression while on a lenalidomide-based treatment used for multiple myeloma in any setting including in maintenance treatment.
3. Patients requesting lenalidomide as fourth line treatment for multiple myeloma.
4. Patients with monoclonal gammopathy of uncertain significance (MGUS), smoldering myeloma, or primary amyloidosis.

Transition from Off-Formulary Interchangeable (OFI) to Limited Use (Continued)

Recommended Dose: 25mg daily as a single 25mg capsule

Patients should be dispensed the most appropriate strength of lenalidomide to achieve the dose recommendation and with the fewest number of tablets per day.

Note: Pharmacists and prescribers should be informed of a drug product's official indications and recommended dosage as set out in Health Canada's approved product monograph. Some aspects of this criteria may differ from the official indications and recommended dosage as described in the product monographs for lenalidomide or other products that may be used as part of combination therapy with lenalidomide. The Executive Officer's funding of drug products is informed by advice from expert committees that consider evidence regarding the safety, clinical efficacy, and cost-effectiveness of the drug products. Where there is a difference between a product monograph and the LU criteria described above, the LU criteria governs for the purpose of funding under the Ontario Drug Benefit Program.

Manufacturer Name Changes

DIN/PIN	Brand Name	Strength	Dosage Form	Current Mfr	New Mfr
02499509	Nexplanon	68mg/Implant	ER Subdermal Implant	MEK	OCI

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Product Brand and Manufacturer Name Changes

DIN/PIN	Current Brand Name	Current Mfr	New Brand Name	New Mfr	Strength	Dosage Form
02230431	Metonia	PEN	PMS-Metoclopramide Tablets	PMS	5mg	Tab
02230432	Metonia	PEN	PMS-Metoclopramide Tablets	PMS	10mg	Tab

Drug Benefit Price (DBP) Changes

To view the DBP changes by DIN/PIN, the ministry has posted an Excel file with the details of the listing changes for download and review (Edition 43: Summary of Changes–Drug Benefit Price Changes–April 29, 2022). It is accessible from the ministry's website: http://www.health.gov.on.ca/en/pro/programs/drugs/edition_43.aspx.

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Discontinued Products

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

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02163152	Lidemol	0.05%	Emol Cr	VAE
02161923	Lidex	0.05%	Cr	VAE
02161974	Lidex	0.05%	Gel	VAE
02161966	Lidex	0.05%	Oint	VAE

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Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
00604402	Glysennid	8.6mg	Tab	NOV
02421488	PMS-Levocarb CR	100mg & 25mg	CR Tab	PMS
02421496	PMS-Levocarb CR	200mg & 50mg	CR Tab	PMS
02428725	Van-Alendronate	10mg	Tab	VAN
02426986	Van-Amlodipine	5mg	Tab	VAN
02426994	Van-Amlodipine	10mg	Tab	VAN
02427818	Van-Anastrozole	1mg	Tab	VAN
02428709	Van-Bicalutamide	50mg	Tab	VAN
02426978	Van-Ciprofloxacin	250mg	Tab	VAN
02427001	Van-Ciprofloxacin	500mg	Tab	VAN
02427028	Van-Ciprofloxacin	750mg	Tab	VAN
02438747	Van-Citalopram	20mg	Tab	VAN
02438755	Van-Citalopram	40mg	Tab	VAN
02426943	Van-Donepezil	5mg	Tab	VAN
02426951	Van-Donepezil	10mg	Tab	VAN
02451271	Van-Dorzolamide-Timolol	2% & 0.5%	Oph Sol	VAN
02432420	Van-Fluoxetine	20mg	Cap	VAN
02431408	Van-Gabapentin	100mg	Cap	VAN
02431416	Van-Gabapentin	300mg	Cap	VAN
02431424	Van-Gabapentin	400mg	Cap	VAN
02427087	Van-Irbesartan	75mg	Tab	VAN
02427095	Van-Irbesartan	150mg	Tab	VAN
02427109	Van-Irbesartan	300mg	Tab	VAN
02428156	Van-Letrozole	2.5mg	Tab	VAN
02426595	Van-Losartan	25mg	Tab	VAN
02426609	Van-Losartan	50mg	Tab	VAN
02426617	Van-Losartan	100mg	Tab	VAN
02063662	MacroBID	100mg	Cap	WAR