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Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – September 2022
Effective September 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: TERIPARATIDE

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02495589	Osnuvo	250mcg/mL	Inj Sol-3mL Cart Pk	AVP	565.2600/Cart

Reason For Use Code and Clinical Criteria

Code 635

For the treatment of osteoporosis in patients at a high risk of fragility fractures who meet ALL the following criteria:

- 65 years of age or older; AND
- Has a documented bone mineral density [BMD] T-score of less than or equal to 3; AND
- Has a history of prior fragility fracture(s); AND
- Has used an anti-resorptive agent for osteoporosis which resulted in osteonecrosis of the jaw and/or an atypical femur fracture.

Note: The maximum lifetime exposure to teriparatide for an individual patient is 24 months

LU Authorization Period: 2 years

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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
02462060	Drospirenone & Ethinyl Estradiol Tablets USP	3.0mg & 0.02mg	Tab-28 Pk	GLP	8.2600/Pk

(Interchangeable with Yaz – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02524856	Gliclazide MR	30mg	ER Tab	SAI	0.0931
02524864	Gliclazide MR	60mg	ER Tab	SAI	0.0632

(Interchangeable with Diamicron MR – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02500175	Jamp Alendronate Sodium	70mg	Tab	JPC	1.7804

(Interchangeable with Fosamax – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02498502	Jamp Digoxin	0.0625mg	Tab	JPC	0.1850
02498510	Jamp Digoxin	0.125mg	Tab	JPC	0.1751

(Interchangeable with Toloxin – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02516799	Jamp Temozolomide	5mg	Cap	JPC	1.9500
02516802	Jamp Temozolomide	20mg	Cap	JPC	7.8000
02516810	Jamp Temozolomide	100mg	Cap	JPC	39.0015
02516829	Jamp Temozolomide	140mg	Cap	JPC	54.6025
02516845	Jamp Temozolomide	250mg	Cap	JPC	97.5010

(Interchangeable with Temodal – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02496836	Jamp Tolterodine	1mg	Tab	JPC	0.2455
02496844	Jamp Tolterodine	2mg	Tab	JPC	0.2455

(Interchangeable with Detrol – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02524244	Letrozole	2.5mg	Tab	SIV	1.3780

(Interchangeable with Femara – GB)

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New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02521938	Jamp Ambrisentan	5mg	Tab	JPC	106.3288
02521946	Jamp Ambrisentan	10mg	Tab	JPC	106.3288

(Interchangeable with Volibris)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02506866	Jamp Atomoxetine	80mg	Cap	JPC	3.9960
02506874	Jamp Atomoxetine	100mg	Cap	JPC	4.3520

(Interchangeable with Strattera)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02517604	PMS-Cinacalcet	30mg	Tab	PMS	10.1947
02517612	PMS-Cinacalcet	60mg	Tab	PMS	18.5900
02517620	PMS-Cinacalcet	90mg	Tab	PMS	27.0517

(Interchangeable with Sensipar)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02525666	PMS-Pazopanib	200mg	Tab	PMS	30.9655

(Interchangeable with Votrient)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02524058	Taro-Sunitinib	12.5mg	Cap	TAR	55.3553
02524066	Taro-Sunitinib	25mg	Cap	TAR	110.7100
02524082	Taro-Sunitinib	50mg	Cap	TAR	221.4208

(Interchangeable with Sutent)

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Revisions of Limited Use Criteria

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02459418	Revlimid	2.5mg	Cap	CEL
02507927	Apo-Lenalidomide	2.5mg	Cap	APX
02506130	Jamp Lenalidomide	2.5mg	Cap	JPC
02493837	Nat-Lenalidomide	2.5mg	Cap	NAT
02484714	Reddy-Lenalidomide	2.5mg	Cap	DRR
02518562	Sandoz Lenalidomide	2.5mg	Cap	SDZ
02507862	Taro-Lenalidomide	2.5mg	Cap	TAR

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02304899	Revlimid	5mg	Cap	CEL
02507935	Apo-Lenalidomide	5mg	Cap	APX
02506149	Jamp Lenalidomide	5mg	Cap	JPC
02493845	Nat-Lenalidomide	5mg	Cap	NAT
02483017	Reddy-Lenalidomide	5mg	Cap	DRR
02518570	Sandoz Lenalidomide	5mg	Cap	SDZ
02507870	Taro-Lenalidomide	5mg	Cap	TAR

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02304902	Revlimid	10mg	Cap	CEL
02507943	Apo-Lenalidomide	10mg	Cap	APX
02506157	Jamp Lenalidomide	10mg	Cap	JPC
02493861	Nat-Lenalidomide	10mg	Cap	NAT
02483025	Reddy-Lenalidomide	10mg	Cap	DRR
02518589	Sandoz Lenalidomide	10mg	Cap	SDZ
02507889	Taro-Lenalidomide	10mg	Cap	TAR

Revisions of Limited Use Criteria (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02317699	Revlimid	15mg	Cap	CEL
02507951	Apo-Lenalidomide	15mg	Cap	APX
02506165	Jamp Lenalidomide	15mg	Cap	JPC
02493888	Nat-Lenalidomide	15mg	Cap	NAT
02483033	Reddy-Lenalidomide	15mg	Cap	DRR
02518597	Sandoz Lenalidomide	15mg	Cap	SDZ
02507897	Taro-Lenalidomide	15mg	Cap	TAR

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02440601	Revlimid	20mg	Cap	CEL
02507978	Apo-Lenalidomide	20mg	Cap	APX
02506173	Jamp Lenalidomide	20mg	Cap	JPC
02493896	Nat-Lenalidomide	20mg	Cap	NAT
02483041	Reddy-Lenalidomide	20mg	Cap	DRR
02518600	Sandoz Lenalidomide	20mg	Cap	SDZ
02507900	Taro-Lenalidomide	20mg	Cap	TAR

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02317710	Revlimid	25mg	Cap	CEL
02507986	Apo-Lenalidomide	25mg	Cap	APX
02506181	Jamp Lenalidomide	25mg	Cap	JPC
02493918	Nat-Lenalidomide	25mg	Cap	NAT
02483068	Reddy-Lenalidomide	25mg	Cap	DRR
02518619	Sandoz Lenalidomide	25mg	Cap	SDZ
02507919	Taro-Lenalidomide	25mg	Cap	TAR

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

Revisions of Limited Use Criteria (Continued)

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 dexamethasone and bortezomib (Note 2); OR as part of a triplet regimen in combination with dexamethasone and daratumumab (Note 3) OR
   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).

LU Authorization Period: 1 year

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 2.5mmol/L) that can be attributed solely to the plasma cell proliferative disorder.

Revisions of Limited Use Criteria (Continued)

2. Patients with multiple myeloma who experience disease progression on a lenalidomide-bortezomib-dexamethasone triplet will not be eligible for further bortezomib-based regimens subsequent to disease progression, in any multiple myeloma settings. Patients with multiple myeloma who experience disease progression on a lenalidomide-daratumumab-dexamethasone triplet will not be eligible for further daratumumab-based regimens subsequent to disease progression, in any multiple myeloma setting.

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.

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.

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.

Revisions of Limited Use Criteria (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.

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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
09854231	Compleat	NON	Compleat 1.06	NES		Liq-1000mL Ready-To-Hang

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Drug Benefit Price (DBP) Changes

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP/Unit Price
02498685	Atectura Breezhaler	150mcg & 80mcg	Inh Pd-Cap	NOV	1.0731
02498707	Atectura Breezhaler	150mcg & 160mcg	Inh Pd-Cap	NOV	1.3419
02498693	Atectura Breezhaler	150mcg & 320mcg	Inh Pd-Cap	NOV	1.8473
02504170	Jamp Teriflunomide	14mg	Tab	JPC	50.7620
00012750	Matulane	50mg	Cap	LBI	77.5199
02394596	Methadose	10mg/mL	Oral Concentrate (Cherry Flavour)	MAL	0.0525/mL
02394618	Methadose	10mg/mL	Oral Concentrate (Unflavoured)	MAL	0.0525/mL
02423308	Mint-Tolterodine	1mg	Tab	MIN	0.2455
02423316	Mint-Tolterodine	2mg	Tab	MIN	0.2455
02415380	MYA	3.0mg & 0.02mg	Tab-28 Pk	APX	8.2600
02317966	Purg-Odan	3.5g & 12g & 10mg	Pd for Sol-12g Sachet	ODN	10.2000
02125706	Soothe Night Time	80%/20%	Oph Oint-3.5g Pk	BLI	5.4800
02443473	Taro-Temozolomide	5mg	Cap	TAR	1.9500
02443481	Taro-Temozolomide	20mg	Cap	TAR	7.8000
02443511	Taro-Temozolomide	100mg	Cap	TAR	39.0015
02443538	Taro-Temozolomide	140mg	Cap	TAR	54.6025
02443554	Taro-Temozolomide	250mg	Cap	TAR	97.5010
02441160	Teva-Temozolomide	5mg	Cap	TEV	1.9500
02395274	Teva-Temozolomide	20mg	Cap	TEV	7.8000
02395282	Teva-Temozolomide	100mg	Cap	TEV	39.0015
02395290	Teva-Temozolomide	140mg	Cap	TEV	54.6025
02395312	Teva-Temozolomide	250mg	Cap	TEV	97.5010
02299593	Teva-Tolterodine	1mg	Tab	TEV	0.2455
02299607	Teva-Tolterodine	2mg	Tab	TEV	0.2455

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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
02369362	Acuvail	0.45%	Oph Sol-0.4mL Vial Pk	ALL
02239653	Androderm	12.2mg	Transdermal Patch	WAT
00299405	Pred Mild	0.12%	Oph Susp	ALL

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Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02281228	Apo-Digoxin	0.125mg	Tab	APX
02281201	Apo-Digoxin	0.25mg	Tab	APX
00786535	Dilaudid	1mg/mL	Oral Sol	PFP
02218453	Ratio-Fluvoxamine	50mg	Tab	RPH
00329320	Sandomigran	0.5mg	Tab	PAL
02269317	Teva-Pramipexole	0.5mg	Tab	TEV
02269325	Teva-Pramipexole	1mg	Tab	TEV
02269333	Teva-Pramipexole	1.5mg	Tab	TEV