Formulary Search - Limited Use Note(s) (gov.on.ca)

Search Completed on August 15, 2024

ZOLEDRONIC ACID 5mg/100mL Inj Sol-100mL Pk (Preservative-Free)

Formulary Search - Limited Use Note(s) (gov.on.ca)

Reason For Use Code	Clinical Criteria
319	For the treatment of Paget's disease.
	LU Authorization Period: Indefinite.

436	For the treatment of osteoporosis in **postmenopausal females** who meet the following criteria:
	• High risk* for fracture; and
	  ○ For whom oral bisphosphonates are contraindicated due to abnormalities of the esophagus (e.g. esophageal stricture or achalasia) OR
	  ○ inability to stand or sit upright for at least 30 minutes.
	
	*High fracture risk is defined as either:
	• a prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool; OR - a high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR
	• where a patient's 10-year fracture risk based on the CAROC or FRAX tool, is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture
	
	Note: Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.

	LU Authorization Period: Indefinite.

523	For the treatment of osteoporosis in **males** who meet the following criteria:
	• High risk* for fracture; and
	  ○ For whom oral bisphosphonates are contraindicated due to abnormalities of the esophagus (e.g. esophageal stricture or achalasia) OR
	  ○ inability to stand or sit upright for at least 30 minutes.
	
	*High fracture risk is defined as either:
	• a moderate 10-year fracture risk (10% to 20%) with a prior fragility fracture based on the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool; OR
	• a high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR
	• where the patient's 10-year fracture risk is below 10% based on the CAROC or FRAX tool, a high fracture risk based on evaluation of clinical risk factors for fracture

	Note: Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.
	LU Authorization Period: Indefinite.
	NOTE: In all cases, patients receiving Aclasta should not be receiving concomitant bisphosphonate therapy. The recommended dose of Aclasta (zoledronic acid) is a single IV injection of 5mg, once yearly.

Products found: 13

DIN/ PIN/ NPN	Generic Name	Brand Name, Strength & Dosage Form	MFR	Drug Benefit Price or Unit Price	Amount MOH Pays	Inter-change-able	Limited Use	Thera-peutic Notes
02269198	ZOLEDRONIC ACID	Aclasta 5mg/100mL Inj Sol-100mL Pk (Preservative-Free)	SDZ	833.7300	**356.0100**	YES	YES	NO
02415100	ZOLEDRONIC ACID	Taro-Zoledronic Acid 5mg/100mL Inj Sol-100mL Pk (Preservative-Free)	TAR	356.0100	**356.0100**	YES	YES	NO
02422433	ZOLEDRONIC ACID	Zoledronic Acid Injection 5mg/100mL Inj Sol-100mL Pk (Preservative-Free)	DRR	356.0100	**356.0100**	YES	YES	NO
02482525	ZOLEDRONIC ACID	Jamp-Zoledronic Acid (Off-Formulary Interchangeable) 4mg/5mL Inj Sol-5mL Pk (Preservative-Free)	JPC	415.5600	**415.5600**	YES	NO	NO
02415186	ZOLEDRONIC ACID	Taro-Zoledronic Acid Concentrate (Off-Formulary Interchangeable) 4mg/5mL Inj Sol-5mL Pk (Preservative-Free)	TAR	415.5600	**415.5600**	YES	NO	NO

02413701	ZOLEDRONIC ACID	Zoledronic Acid for Inj. Concentrate (Off-Formulary Interchangeable) 4mg/5mL Inj Sol-5mL Pk (Preservative-Free)	OMG	415.0000	**415.0000**	YES	NO	NO
02422425	ZOLEDRONIC ACID	Zoledronic Acid for Inj. Concentrate (Off-Formulary Interchangeable) 4mg/5mL Inj Sol-5mL Pk (Preservative-Free)	DRR	415.5600	**415.5600**	YES	NO	NO
02472805	ZOLEDRONIC ACID	Zoledronic Acid for Injection (Off-Formulary Interchangeable) 4mg/5mL Inj Sol-5mL Pk (Preservative-Free)	MAR	415.5600	**415.5600**	YES	NO	NO
02434458	ZOLEDRONIC ACID	Zoledronic Acid for Injection (Off-Formulary Interchangeable) 4mg/5mL Inj Sol-5mL Pk (Preservative-Free)	FKC	415.5600	**415.5600**	YES	NO	NO
02444739	ZOLEDRONIC ACID	Zoledronic Acid for Injection (Off-Formulary Interchangeable) 4mg/5mL Inj Sol-5mL Pk (Preservative-Free)	MDI	415.5600	**415.5600**	YES	NO	NO
02407639	ZOLEDRONIC ACID	Zoledronic Acid for Injection (Off-Formulary Interchangeable) 4mg/5mL Inj Sol-5mL Pk	TEV	415.5600	**415.5600**	YES	NO	NO

		(Preservative-Free)						
02401606	ZOLEDRONIC ACID	Zoledronic Acid-Z (Off-Formulary Interchangeable) 4mg/5mL Inj Sol-5mL Pk (Preservative-Free)	SDZ	415.5600	**415.5600**	YES	NO	NO
02248296	ZOLEDRONIC ACID	Zometa Concentrate (Off-Formulary Interchangeable) 4mg/5mL Inj Sol-5mL Pk (Preservative-Free)	NOV	N/A	**N/A**	YES	NO	NO

DENOSUMAB 60mg/mL Inj Sol-Pref Syr

Reason For Use Code	Clinical Criteria

428	To increase bone mass in **postmenopausal females** with osteoporosis who meet the following criteria:
	• High risk* for fracture; and
	  ○ Failed other available osteoporosis therapy (i.e. fragility fracture OR
	  ○ evidence of a decline in bone mineral density below pre-treatment baseline levels) despite adherence for one year.
	
	*High fracture risk is defined as either:
	• a prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool; OR
	• a high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR
	• where a patient's 10-year fracture risk based on the CAROC or FRAX tool is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture
	
	Note: Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.

	LU Authorization Period: Indefinite.
	NOTE: In all cases, patients receiving Prolia must not be receiving concomitant bisphosphonate therapy. The recommended dose of PROLIA (denosumab) is a single SC injection of 60 mg, once every 6 months.

429	To increase bone mass in **postmenopausal females** with osteoporosis who meet the following criteria:
	• High risk* for fracture; and
	  ○ For whom oral bisphosphonates are contraindicated due to hypersensitivity OR
	  ○ abnormalities of the esophagus (e.g. esophageal stricture or achalasia) OR
	  ○ inability to stand or sit upright for at least 30 minutes.
	
	*High fracture risk is defined as either:
	• a prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool; OR
	• a high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR
	• where a patient's 10-year fracture risk based on the CAROC or FRAX tool is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture

	Note: Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.
	LU Authorization Period: Indefinite.
	NOTE: In all cases, patients receiving Prolia must not be receiving concomitant bisphosphonate therapy. The recommended dose of PROLIA (denosumab) is a single SC injection of 60 mg, once every 6 months.

515	To increase bone mass in **males** with osteoporosis who meet the following criteria:
	• High risk* for fracture; and
	  ○ Failed other available osteoporosis therapy (i.e. fragility fracture OR
	  ○ evidence of a decline in bone mineral density below pre-treatment baseline levels) despite adherence for one year.
	
	*High fracture risk is defined as either:
	• a prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool; OR
	• a high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR
	• where a patient's 10-year fracture risk based on the CAROC or FRAX tool is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture
	
	Note: Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.

	LU Authorization Period: Indefinite.
	NOTE: In all cases, patients receiving Prolia must not be receiving concomitant bisphosphonate therapy. The recommended dose of PROLIA (denosumab) is a single SC injection of 60 mg, once every 6 months.

516	To increase bone mass in **males** with osteoporosis who meet the following criteria:
	• High risk* for fracture; and
	  ○ For whom oral bisphosphonates are contraindicated due to hypersensitivity OR
	  ○ abnormalities of the esophagus (e.g. esophageal stricture or achalasia) OR
	  ○ inability to stand or sit upright for at least 30 minutes.
	*High fracture risk is defined as either:
	• a prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool; OR
	• a high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR
	• where a patient's 10-year fracture risk based on the CAROC or FRAX tool is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture
	
	Note: Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.

	LU Authorization Period: Indefinite.

	NOTE: In all cases, patients receiving Prolia must not be receiving concomitant bisphosphonate therapy. The recommended dose of PROLIA (denosumab) is a single SC injection of 60 mg, once every 6 months.

Products found: 1

DIN/ PIN/ NPN	Generic Name	Brand Name, Strength & Dosage Form	MFR	Drug Benefit Price or Unit Price	Amount MOH Pays	Inter-change-able	Limited Use	Thera-peutic Notes
02343541	DENOSUMAB	Prolia (Preservative Free) 60mg/mL Inj Sol-Pref Syr	AMG	440.1000	**440.1000**	NO	YES	NO

RALOXIFENE HCL60mg Tab

Reason For Use Code	Clinical Criteria
	For the treatment of osteoporosis in **postmenopausal women** who have:
373	Failed or, experienced intractable side effects, or have a contraindication to, alendronate OR risedronate.
	Failure is defined as: continued loss of bone mineral density (loss of more than 3%) after two years of therapy; or a new osteoporosis related fracture after one year of therapy.
	LU Authorization Period: Indefinite.

Products found: 3

DIN/ PIN/ NPN	Generic Name	Brand Name, Strength & Dosage Form	MFR	Drug Benefit Price or Unit Price	Amount MOH Pays	Inter-change-able	Limited Use	Thera-peutic Notes
02279215	RALOXIFENE HCL	Apo-Raloxifene 60mg Tab	APX	1.0268	**1.0268**	YES	YES	NO
02358840	RALOXIFENE HCL	Co Raloxifene 60mg Tab	COB	1.0268	**1.0268**	YES	YES	NO
02239028	RALOXIFENE HCL	Evista 60mg Tab	LIL	2.2625	**1.0268**	YES	YES	NO

TERIPARATIDE250mcg/mL Inj Sol-2.4mL Pref Pen – FORTEO

Reason For Use Code	Clinical Criteria
676	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

TERIPARATIDE250mcg/mL Inj Sol-3mL Cart Pk - OSNUVO

Reason For Use Code	Clinical Criteria
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

Products found: 3

DIN/ PIN/ NPN	Generic Name	Brand Name, Strength & Dosage Form	MFR	Drug Benefit Price or Unit Price	Amount MOH Pays	Inter-change-able	Limited Use	Thera-peutic Notes
09857535	TERIPARATIDE	Forteo 250mcg/mL Inj Sol-2.4mL Pref Pen	LIL	1179.8500	**535.4700**	YES	YES	NO
02486423	TERIPARATIDE	Teva-Teriparatide Injection 250mcg/mL Inj Sol-2.4mL Pref Pen	TEV	535.4700	**535.4700**	YES	YES	NO
02495589	TERIPARATIDE	Osnuvo 250mcg/mL Inj Sol-3mL Cart Pk	AVP	565.2600	**565.2600**	NO	YES	NO

Romosozumab

ProVital Patient Support Program for EVENITY

OSTEOPOROSIS

Romosozumab
Brand(s): Evenity
DOSAGE FORM/ STRENGTH: 90 mg/mL
Effective date: October 11, 2023

For the treatment of osteoporosis in postmenopausal women meeting ALL the following criteria:

1. History of osteoporotic fracture; AND
2. Is at a high risk for future fracture, defined as a 10-year fracture risk greater than or equal to 20% as defined by the Fracture Risk Assessment (FRAX) Tool; AND
3. Treatment naive to osteoporosis medications, except for calcium and/or vitamin D.

Exclusion criteria:

Romosozumab will not be funded as combination therapy with other osteoporosis medications, except for calcium and/or vitamin D.

Recommended dose:

210 mg subcutaneously once every month for 12 doses

Approval duration: 12 months (A maximum of 12 monthly doses will be reimbursed.)

Renewals will not be considered.

Note: Requesting prescriber must include a copy of the FRAX assessment.

Request for an Unlisted Drug Product - Exceptional Access Program (EAP)

For faster decisions, prescribers can use the SADIE online portal to submit requests to the Exceptional Access Program (EAP). Sign in through GO Secure (https://www.ebse.health.gov.on.ca) and select SADIE from the services drop-down menu. Visit the SADIE website for more information: http://www.ontario.ca/sadie. Alternatively, this form can be used for submitting requests to the EAP by fax.

https://forms.mgcs.gov.on.ca/dataset/014-4406-87

Forms, Links, and Information

- English / French - 014-4406-87B - Request for an Unlisted Drug...PDF

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- English - 014-4406-87E - Request for an Unlisted Drug Product -...HTML

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- French - 014-4406-87F - Request for an Unlisted Drug Product -...HTML

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Additional Information

Form Number	014-4406-87
Title	Request for an Unlisted Drug Product - Exceptional Access Program (EAP)
Description	For faster decisions, prescribers can use the SADIE online portal to submit requests to the Exceptional Access Program (EAP). Sign in through GO Secure (https://www.ebse.health.gov.on.ca) and select SADIE from the services drop-down menu. Visit the SADIE website for more information: http://www.ontario.ca/sadie. Alternatively, this form can be used for submitting requests to the EAP by fax.