Washington State Health Care Authority

Bone Density Regulators – Calcitonins

Medical policy no. 30.04.30-2 Effective Date: Month, 1, Year

Related medical policies:

Policy Name	Indications
Bone Density Regulators – Sclerostin Inhibitors	Osteoporosis/Bone loss
Bone Density Regulators – Parathyroid Hormone Derivatives	Glucocorticoid Induced Osteoporosis Male Osteoporosis Postmenopausal Osteoporosis
Bone Density Regulators- RANKL Inhibitors	Giant cell tumor of bone Glucocorticoid Induced Osteoporosis Hypercalcemia of malignancy Multiple Myeloma and bone metastasis from solid tumors Postmenopausal Osteoporosis Treatment of bone loss in men prostate cancer Treatment of bone loss in women with breast cancer

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	Medical Necessity
Calcitonin-salmon (Miacalcin)	**Calcitonin-salmon (Miacalcin)** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. • Non-preferred brand name products on the Apple Health Preferred Drug List with an A-rated generic equivalent must also meet criteria in Non-Clinical Policy No. 0001 (NC-001). If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

<table>
<tr><th colspan="2">Clinical Criteria</th></tr>
<tr><td>Hypercalcemia
Calcitonin-salmon (Miacalcin)</td><td>Calcitonin-salmon (Miacalcin) may be approved when all the following documented criteria are met: **SEE NOTE ON SIDE**
1. Patient is 18 years of age or older; AND
2. Diagnosis of hypercalcemia;

If ALL criteria are met, the request will be authorized for 6 months.

Criteria (Reauthorization)
Calcitonin-salmon (Miacalcin) may be approved when all the following documented criteria are met:

1. Not used in combination with <DRUG(S)>; AND
2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., list examples of improvements here].

If ALL criteria are met, the request will be authorized for ## months.</td></tr>
<tr><td>Paget's Disease
Calcitonin-salmon (Miacalcin)</td><td>Calcitonin-salmon (Miacalcin) may be approved when all the following documented criteria are met:
1. Patient is 18 years of age or older; AND
2. Diagnosis of Paget's Disease; AND
3. Patient has symptomatic disease (e.g., bone pain, nerve compression, bone lesions, fracture); AND
4. Baseline assessments of either of the following are included:
a. Serum alkaline phosphatase (sAP); OR
b. Diagnostic radiograph, CT or MRI; OR
c. Biopsy results; AND
5. Treatment with at least one Preferred Apple Health Preferred Drug List (PDL) oral or intravenous bisphosphonate medication has been ineffective unless all are contraindicated or not tolerated [minimum trial of 12 months]

If ALL criteria are met, the request will be authorized for 12 months.

Criteria (Reauthorization)
Calcitonin-salmon (Miacalcin) may be approved when all the following documented criteria are met:

1. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in sAP, bone pain).

If ALL criteria are met, the request will be authorized for 12 months.</td></tr>
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Postmenopausal Osteoporosis Calcitonin-salmon (Miacalcin)	Calcitonin-salmon (Miacalcin) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Diagnosis of osteoporosis; **AND** 3. Patient is a postmenopausal female; **AND** 4. At least **ONE** of the following fracture risk categories is met: a. Presence of fragility fractures of the hip or spine regardless of bone mineral density; **OR** b. T-score ≤ -2.5 in the lumbar spine, femoral neck, total hip; **OR** c. T-score between -1 and -2.5 with a history of recent fragility fracture of proximal humerus, pelvis, or distal forearm; **OR** d. T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; **AND** 5. History of at least **ONE** of the following: a. Treatment with at least one Preferred Apple Health Preferred Drug List (PDL) oral or intravenous bisphosphonate medication has been ineffective unless all are contraindicated or not tolerated [minimum trial of 12 months]; **OR** b. Treatment with at least one Preferred Apple Health Preferred Drug List (PDL) selective estrogen receptor modulator (SERM) medication has been ineffective unless all are contraindicated, or not tolerated [minimum trial of 24 months]. If ALL criteria are met, the request will be authorized for **12 months.**
	Criteria (Reauthorization) Calcitonin-salmon (Miacalcin) may be approved when all the following documented criteria are met: 1. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., patient has not suffered a fragility fracture, bone mineral density continues to improve/remain stable). If ALL criteria are met, the request will be authorized for **12 months.**

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Miacalcin (Brand)	Hypercalcemia	4 IU/kg subcutaneously or intramuscularly every 12 hours; may increase after 1-2 days to 8 IU/kg every 12 hours	• 400IU/2mL vial: Dosing is weight dependent.

Miacalcin (Brand) **Miacalcin (Brand)**	Paget's Disease Postmenopausal osteoporosis	100 IU intramuscularly or subcutaneously daily	• 400IU/2mL vial: 14 mL/28 days
Calcitonin-salmon (generic)	Hypercalcemia	4 IU/kg subcutaneously or intramuscularly every 12 hours; may increase after 1-2 days to 8 IU/kg every 12 hours	• 400IU/2mL vial: Dosing is weight dependent.
Calcitonin-salmon (generic)	Paget's Disease Postmenopausal osteoporosis	100 IU intramuscularly or subcutaneously daily	• 400IU/2mL vial: 14 mL/28 days •
Calcitonin-salmon (generic)	Postmenopausal osteoporosis	200 IU (1 spray) intranasally per day, alternating nostrils daily	• 200IU nasal spray/1 actuation (3.7 mL bottle): 1 bottle/28 days

Coding:

HCPCS Code	Description
<HCPCS Code>	Formulation, generic name, max fill

Background:

Osteoporosis is characterized by decreased bone mass and increased fracture risk, most commonly at the spine, hip, and wrist. The definition of osteoporosis with high risk of fracture is defined for men and women as BMD T-score of spine, femoral neck, and/or total hip <-2.5 without fracture, having history of hip or vertebral fracture regardless of BMD, T-score ≤ -1 and a history of recent fracture of proximal humerus, pelvis, or distal forearm, T-score between -1.0 and -2.5 in the spine, femoral neck, or total hip with a -20% 10-year FRAX risk of any fracture or -3% risk of hip fracture, and receiving long-term glucocorticoid doses greater than or equal to prednisone 7.5mg per day. The treatment of osteoporosis consists of lifestyle management (e.g., adequate calcium and vitamin D, exercise, smoking cessation, fall prevention measures, and avoidance of heavy alcohol use) and pharmacologic therapy. Patients with the highest risk of fracture are expected to derive the greatest benefit from medication therapy. The 2020 AACE/ACE treatment guideline recommendations are as follows:

1. Initial treatment for high fracture risk: alendronate, denosumab, risedronate, or zoledronic acid
2. Treatment for very-high fracture risk or patients who cannot tolerate or adhere to oral bisphosphonates: zoledronic acid, abaloparatide, denosumab, romosozumab, teriparatide

Additionally, the 2020 Endocrine Society guidelines recommend bisphosphonates as initial treatment for high-risk patients, while denosumab may be considered as an alternative initial treatment. For patients with a very high risk of fracture, teriparatide and abaloparatide are recommended. It is recommended that antiresorptive therapies follow treatment with parathyroid hormones.

References

1. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis-2020 update. Endocr Pract. 2020;26(Suppl 1):1-46.
2. Shoback D, Rosen CJ, Black DM, Cheung AM, Murad MH, Eastell R. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society guideline update. J Clin Endocrinol Metab. 2020;105(3):dgaa048.

History

Approved Date	Effective Date	Version	Action and Summary of Changes
MM/DD/YYY	MM/DD/YYYY	30.04.30-2	Pending Approval (draft/unpublished version) -New policy created after Bone Density Regulator policy breakout

Washington State Health Care Authority

Calcitonins

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. Is this request for a continuation of existing therapy? ☐ Yes ☐ No
   If yes, is there documentation demonstrating disease stability or a positive clinical response (e.g., improvement in sAP, bone pain, patient has not suffered a fragility fracture, bone mineral density continues to improve/remain stable)? ☐ Yes ☐ No

2. Indicate patient's diagnosis:
   - ☐ Hypercalcemia
   - ☐ Paget's Disease
   - ☐ Postmenopausal Osteoporosis
   - ☐ Other, specify: _____

3. Has the patient been treated with at least one Apple Health Preferred Drug (oral or intravenous) unless ineffective, contraindicated or not tolerated? Check all that apply:
   - ☐ Bisphosphonate (minimum trial of 12 months), specify: _____
   - ☐ Selective estrogen receptor modulator (SERM) (minimum trial of 24 months), specify: _____
   - ☐ Other, specify: _____

For Paget's Disease:

4. Which of the following symptomatic disease has the patient experienced?
   - ☐ Bone Lesions
   - ☐ Bone Pain
   - ☐ Fracture
   - ☐ Nerve Compression

5. Have the baseline assessments been completed using any of following? Check all that apply:
   - ☐ Biopsy results
   - ☐ Diagnostic radiograph, CT or MRI
   - ☐ Serum alkaline phosphatase (sAP)

For Postmenopausal Osteoporosis

6. Indicate if patient has any of the following:
   - ☐ Presence of fragility fractures of the hip or spine regardless of bone mineral density
   - ☐ T-score ≤ -2.5 in the lumbar spine, femoral neck, total hip
   - ☐ T-score between -1 and -2.5 with a history of recent fragility fracture of proximal humerus, pelvis, or distal forearm

☐ T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%
CHART NOTES, LABS AND ASSESMENTS ARE REQUIRED WITH THIS REQUEST

Prescriber signature	Prescriber specialty	Date