

## SPECIALTY GUIDELINE MANAGEMENT

### MIACALCIN (calcitonin [salmon] injection)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

###### A. FDA-Approved Indications

1. Miacalcin injection is indicated for the treatment of symptomatic Paget's disease of bone in patients with moderate to severe disease characterized by polyostotic involvement with elevated serum alkaline phosphatase and urinary hydroxyproline excretion. There is no evidence that the prophylactic use of calcitonin salmon is beneficial in asymptomatic patients. Miacalcin injection should be used only in patients who do not respond to alternative treatments or for whom such treatments are not suitable.
2. Miacalcin injection is indicated for the early treatment of hypercalcemic emergencies, along with other appropriate agents, when a rapid decrease in serum calcium is required, until more specific treatment of the underlying disease can be accomplished. It may also be added to existing therapeutic regimens for hypercalcemia such as intravenous fluids and furosemide, oral phosphate or corticosteroids, or other agents.
3. Miacalcin injection is indicated for the treatment of postmenopausal osteoporosis in women greater than 5 years postmenopause. Fracture reduction efficacy has not been demonstrated. Miacalcin injection should be reserved for patients for whom alternative treatments are not suitable.

###### B. Compendial Uses

Management of pain following an osteoporotic vertebral fracture

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. Paget's disease of bone: Supporting chart notes or medical record indicating a failed treatment or intolerance to an injectable bisphosphonate
- B. Postmenopausal osteoporosis: Supporting chart notes or medical record indicating pretreatment T-score, as applicable to section III.
- C. For management of pain following an osteoporotic vertebral fracture: Supporting chart notes or imaging report verifying osteoporotic spinal compression fracture

##### III. CRITERIA FOR INITIAL APPROVAL

###### A. **Paget's disease of bone**

Authorization of 12 months may be granted for treatment of Paget's disease of bone when all of the following criteria are met:

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1. Member has symptoms of Paget's disease of bone (e.g., bone pain, bowing of lower extremity, hearing loss, heart failure, increased cardiac output, osteoarthritis) prior to therapy.
2. Member has failed prior treatment with an injectable bisphosphonate (e.g., pamidronate, zoledronic acid) or is intolerant to previous injectable therapy.

**B. Hypercalcemia**

Authorization of 1 month may be granted for treatment of hypercalcemic emergency when Miacalcin is used in combination with other agent(s) to reduce serum calcium levels.

**C. Postmenopausal osteoporosis**

Authorization of 12 months may be granted for postmenopausal osteoporosis when ALL of the following criteria are met:

1. Member is greater than 5 years postmenopause.
2. Member has a pre-treatment T-score less than or equal to -2.5.
3. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo], denosumab [Prolia]) OR has had an oral bisphosphonate trial of at least 1-year duration.

**D. Management of pain following an osteoporotic vertebral fracture**

Authorization of up to 28 days may be granted for treatment of pain following an osteoporotic vertebral fracture with osteoporosis when all of the following criteria are met:

1. Osteoporotic spinal compression fracture has been verified on imaging with correlating clinical signs and symptoms suggesting an acute injury. The date of imaging must be 0 to 5 days after an identifiable event or onset of symptoms and within 4 weeks of this request.
2. Member is neurologically intact.

**IV. CONTINUATION OF THERAPY**

**A. Paget's disease of bone**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for Paget's disease of bone when member has experienced symptomatic improvement.

**B. Postmenopausal osteoporosis**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for postmenopausal osteoporosis when member has experienced clinical benefit after at least 24 months of therapy with Miacalcin as evidenced by improvement or stabilization in T-score.

**C. Other indications**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**V. REFERENCES**

1. Miacalcin [package insert]. Rockford, IL: Mylan Institutional LLC; July 2018.
2. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. *Endocr Pract.* 2016;22 (Suppl 4):1-42.
3. Singer FR, Bone HG, Hosking DJ, et al. Paget's Disease of Bone: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab* 99(12):4408-4422.
4. Bisphosphonates. *Drug Facts and Comparisons*. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; March 21, 2019. Accessed June 11, 2019.

<b>Reference number(s)</b>
3082-A

5. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2014;25(10): 2359-2381.
6. Jeremiah MP, Unwin BK, Greenwald MH, et al. Diagnosis and management of osteoporosis. *Am Fam Physician*. 2015;92(4):261-268.
7. ACOG Practice Bulletin Number 129: Osteoporosis. *Obstet Gynecol*. 2012;120(3):718-734.
8. National Institute for Health and Care Excellence. Osteoporosis Overview. Last updated February 2018. Available at: <http://pathways.nice.org.uk/pathways/osteoporosis>. Accessed June 11, 2019.
9. Treatment to prevent osteoporotic fractures: an update. Department of Health and Human Services, Agency for Healthcare Research and Quality. 2012; Publication No. 12-EHC023-EF. Available at <https://www.effectivehealthcare.ahrq.gov/lbd.cfm>.
10. FRAX® WHO fracture risk assessment tool. © World Health Organization Collaborating Centre for Metabolic Bone Diseases: University of Sheffield, UK. Available at: <https://www.sheffield.ac.uk/FRAX/>. Accessed June 11, 2019.
11. Fink HA, Gordon G, Buckley L, et al. 2017 American College of Rheumatology Guidelines for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Care Res*. 2017;69:1521-1537.
12. Ensrud KE, Crandall CJ. Osteoporosis. *Ann Intern Med* 2017;167(03):ITC17–ITC32.
13. American Academy of Orthopaedic Surgeons (AAOS). The treatment of symptomatic osteoporotic spinal compression fractures. Rosemont, IL: AAOS; September 24, 2010.