

Policy Title:	Miacalcin (calcitonin salmon) (subcutaneous or intramuscular)		
		Department:	PHA
Effective Date:	04/01/2021		
Review Date:	3/18/2021, 2/17/2022, 3/2/2023, 12/14/2023		

Purpose: To support safe, effective and appropriate use of Miacalcin (calcitonin salmon) injection.

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Miacalcin (calcitonin salmon) injection is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Miacalcin (calcitonin salmon) injection will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

For all indications:

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

- Dose does not exceed FDA approved guidelines; AND

Hypercalcemic emergency

- The requested drug is being prescribed for the early treatment of hypercalcemic emergency not related to a malignancy and the member has tried and failed or has a contraindication or intolerance to cinacalcet.

Paget's disease

- The requested drug is being prescribed for the treatment of symptomatic Paget's disease of bone in a member with moderate to severe disease and the member has tried and failed or has a contraindication or intolerance to both of the following agents: alendronate and pamidronate.

Postmenopausal Osteoporosis

- The requested drug is being prescribed for the treatment of postmenopausal osteoporosis in a member greater than 5 years post menopause and the member has tried and failed, or has a contraindication or intolerance to two of the following agents: zoledronic acid, alendronate, teriparatide, Prolia (denosumab), Xgeva (denosumab).

Continuation of therapy:

- Patient meets all initial criteria for diagnosis requested; AND
- Patient is tolerating treatment and is not experiencing any unacceptable toxicity from the drug; AND
- Patient has disease stabilization or improvement in disease (as defined by established clinical practice guidelines).

Coverage durations:

- Initial coverage: 6 months
- Renewal coverage: 6 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 400 IU)
Paget's Disease of bone and Postmenopausal Osteoporosis	100 units per day	7.5 billable units every 30 days
Hypercalcemia	4 units/kg every 12 hours; if the response to this dose is not satisfactory after one or two days, the dose may be increased to 8 Units/kg every 12 hours. If the response remains unsatisfactory after two more days, the dose may be further increased to a maximum of 8 Units/kg every 6 hours.	192 billable units every 30 days

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug

information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0630	Injection, calcitonin (salmon), up to 400 units

References:

1. Miacalcin [package insert]. Rockford, IL: Mylan Institutional LLC; August 2021. Accessed November 2023
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed March 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed March 2020.
4. Singer FR, Bone III, HG, Hosking DJ, et al. Paget's Disease of Bone: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology & Metabolism* 2014;99(12):4408–4422.