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, 01/04/2024		

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.

Summary of Evidence:

Miacalcin synthetic injection is a calcitonin, indicated for Paget's disease, hypercalcemia, and postmenopausal osteoporosis. In randomized controlled trials, postmenopausal women treated with Miacalcin experienced significant improvements in lumbar spine BMD compared to placebo, with greater increases observed in patients with lower baseline BMD. Additionally, Miacalcin therapy has been associated with a reduction in the incidence of vertebral fractures, particularly in patients with a history of prior fracture or low baseline BMD.

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).

Policy Rationale:
Miacalcin was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Miacalcin according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

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.