Policy Title: Miacalcin (calcitonin salmon) (subcutaneous or intramuscular)  

<table>
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<th>Department: PHA</th>
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<tr>
<td>Effective Date: 04/01/2021</td>
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<tr>
<td>Review Date: 3/18/2021</td>
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<tr>
<td>Revision Date: 3/18/2021</td>
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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

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Dosage/Administration:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
<th>Maximum dose (1 billable unit = 400 IU)</th>
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<tbody>
<tr>
<td>Paget's Disease of bone and Postmenopausal Osteoporosis</td>
<td>100 units per day</td>
<td>7.5 billable units every 30 days</td>
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<tr>
<td>Hypercalcemia</td>
<td>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.</td>
<td>192 billable units every 30 days</td>
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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:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
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<tr>
<td>J0630</td>
<td>Injection, calcitonin (salmon), up to 400 units</td>
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References: