MEDICAID POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
06/15/2011	12/15/2016	9/21/2016

Policy Name	Policy Number
Parenteral Calcium Regulators - pamidronate (Aredia), zoledronic acid (Reclast andZometa), ibandronate (Boniva), denosumab (Prolia and Xgeva), teriparatide (Forteo)	SRx-0021

Policy Type		
☒ Medical	☐ Administrative	☐ Payment

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Calcium Regulators

- Zoledronic acid Infusion (Reclast or Zometa)
- Ibandronate Injection (Boniva)
- Denosumab Injection (Prolia or Xgeva)
- Teriparatide Injection (Forteo)
- Pamidronate Injection (Aredia)

Ohio Medicaid Preferred Drug List
Kentucky Medicaid Preferred Drug List
Just4Me Preferred Drug List

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or StepTherapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the Calcium Regulator (PA) program is to encourage appropriate selection of therapy for patients according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

N/A

D. POLICY

CareSource will approve the use of the medications and consider them as medically necessary when the following criteria have been met:

I. Zoledronic acid (Reclast or Zometa), ibandronate solution (Boniva) and pamidronate (Aredia) are considered medically necessary when criteria are met for **ANY** of the following indications:

A. Hypercalcemia of malignancy when **ALL** of the following are met:
1. *Albumin-corrected serum calcium of 12 mg/dL (3 mmol/L) or greater*
2. *Hypercalcemia due to malignancy*

B. Skeletal metastases from cancer, as indicated by **ALL** of the following:
1. *Standard antineoplastic therapy continues*
2. *Osteolytic bone lesions, bone pain, or metastases from 1 or more of the following:*
   a. *Breast cancer*
   b. *Multiple myeloma*
   c. *For **zoledronic acid use only**,**1 or more** of the following:*
      i. *Prostate cancer, if progression occurred after treatment with at least one form of androgen deprivation therapy*
      ii. *Other solid tumors*

C. Moderate to severe Paget's disease, as indicated by **1 or more** of the following:
1. *Asymptomatic, but likely progression in high-risk areas, as indicated by **1 or more** of the following:*
   a. *Potential compression would cause neurologic syndrome*
   b. *Potential fracture in weight-bearing long bone*
2. *Symptoms from active bone lesions, including **1 or more** of the following:*
   a. *Back pain due to Pagetic radiculopathy or arthropathy*
   b. *Bone pain*
   c. *Fissure fractures*
   d. *Headache with skull involvement*
   e. *Other neurologic syndromes*
3. *Elective surgery planned for Pagetic site*
4. *Hypercalcemia from immobilization*
5. *Serum alkaline phosphatase elevated to 2 or more times upper limit of normal age-specific reference range*

D. Osteoporosis, as indicated by **ALL** of the following:
1. *Oral bisphosphonate medications are not therapeutic option, as indicated by **1 or more** of the following:*
   a. *Esophageal dysmotility or varices*
   b. *Intolerance or failure to trials of 2 or more different oral bisphosphonate drugs*
   c. *Patient not adherent to oral bisphosphonate medications*
   d. *Patient unable to stand or sit upright for 30 to 60 minutes*
2. Osteoporosis, and need for treatment, as indicated by **1 or more** of the following:

a. Documented postmenopausal osteoporosis, as indicated by **1 or more** of the following
    i. *Femoral neck, spine, or total hip bone mineral density T-score minus 2.5 or less*
    ii. *Hip or vertebral fragility (ie, low-trauma) fracture in female older than 50 years*
b. **For zoledronic acid use only**, osteoporosis in male, as indicated by **1 or more** of the following:
    i. *Femoral neck, spine, or total hip bone mineral density T-score minus 2.5 or less*
    ii. *Hip or vertebral fragility fracture in patient older than 50 years*
    iii. *Osteoporosis secondary to hypogonadism and failure of or intolerance to testosterone*
c. **For zoledronic acid use only**, prevention or treatment of glucocorticoid-induced osteoporosis in male or female, as indicated by **ALL** of the following:
    i. Duration of glucocorticoid therapy expected to be **1 or more** of the following:
        1. *Three months or more for male 50 years or older*
        2. *Three months or more for any patient with history of fragility (ie, low-trauma fracture)*
        3. *Three months or more for postmenopausal female*
        4. *Twelve months or more for any patient without history of fragility fracture*
    ii. Daily dose of glucocorticoid, as indicated by **1 or more** of the following:
        1. *Glucocorticoid daily dose equivalent to 7.5 mg or more of prednisone*
        2. *Glucocorticoid daily dose equivalent to 5 mg or more of prednisone and **1 or more** of the following risk factors for fracture:*
            a. *Alcohol intake of 3 or more drinks per day*
            b. *BMI less than 20*
            c. *Current or past history of cigarette smoking*
            d. *Osteoporosis (ie, femoral neck, spine, or total hip bone mineral density T-score minus 2.5 or less)*
            e. *Parental hip fracture*
            f. *Previous or current fracture*
            g. *Rheumatoid arthritis*

E. Prevention of osteoporosis, as indicated by **1 or more** of the following:
1. For **zoledronic acid use only**, prevention of osteoporosis in postmenopausal female unable to tolerate oral bisphosphonates
2. Postmenopausal female with breast cancer on aromatase inhibitor and **1 or more** of the following:
    a. *Bone mineral density T-score less than minus 2.0*
    b. *Current non-traumatic fracture*

   c. *Risk factors for fracture, as indicated by **2 or more** of the following:*
      i. *Age older than 65 years*
      ii. *Alcohol intake of 3 or more drinks per day*
      iii. *Annual decrease of bone mineral density of 10% or more*
      iv. *BMI less than 20*
      v. *Bone mineral density T-score less than minus 1.5*
      vi. *Corticosteroid use of more than 6 months' duration*
      vii. *Current or past history of cigarette smoking*
      viii. *Parental hip fracture*
      ix. *Personal history of fragility or osteoporotic fracture after age 50 years*
3. Male with prostate cancer and **ALL** of the following:
   a. *Age 70 years or older*
   b. *Patient receiving androgen deprivation therapy*
   c. *Risk factors for fracture, as indicated by **2 or more** of the following*
      i. *Alcohol intake of 3 or more drinks per day*
      ii. *Bone mineral density T-score less than minus 1.0*
      iii. *Corticosteroid use of more than 6 months' duration*
      iv. *Current or past history of cigarette smoking*
      v. *Parental hip fracture*
      vi. *Personal history of fragility or osteoporotic fracture after age 50 years*
4. **For zoledronic acid use only**, prevention of glucocorticoid-induced osteoporosis in male or female, as indicated by **ALL** of the following:
   a. *Duration of glucocorticoid therapy expected to be **1 or more** of the following:*
      i. *Three months or more for male 50 years or older*
      ii. *Three months or more for any patient with history of fragility (ie, low-trauma fracture)*
      iii. *Three months or more for postmenopausal female*
      iv. *Twelve months or more*
   b. *Daily dose of glucocorticoid, as indicated by **1 or more** of the following:*
      i. *Glucocorticoid daily dose equivalent to 7.5 mg or more of prednisone*
      ii. *Glucocorticoid daily dose equivalent to 5 mg or more of prednisone and **1 or more** of the following risk factors for fracture:*
         1. *Alcohol intake of 3 or more drinks per day*
         2. *BMI less than 20*
         3. *Current or past history of cigarette smoking*
         4. *Osteoporosis (ie, femoral neck, spine, or total hip bone mineral density T-score minus 2.5 or less)*
         5. *Parental hip fracture*
         6. *Previous or current fracture*
         7. *Rheumatoid arthritis*

II. Teriparatide (Forteo) is considered medically necessary when the **ALL** following criteria are met:
    A. Clinical findings include 1 or more of the following:
        1. *Postmenopausal osteoporosis, as indicated by **1 or more** of the following:*
            a. *Femoral neck, spine, or total hip bone mineral density T-score minus 2.5 or less*
            b. *Hip or vertebral fragility (ie, low-trauma) fracture in female older than 50 years*
        2. *Osteoporosis in males, as indicated by **1 or more** of the following:*
            a. *Femoral neck, spine, or total hip bone mineral density T-score minus 2.5 or less*
            b. *Hip or vertebral fragility fracture in patient older than 50 years*
            c. Osteoporosis secondary to hypogonadism and failure of or intolerance to testosterone
        3. Glucocorticoid-induced osteoporosis in male or female, as indicated by **ALL** of the following
            a. Daily dose equivalent to 7.5 mg or more of prednisone
            b. Duration of glucocorticoid therapy expected to be **1 or more** of the following:
                i. Three months or more for male 50 years or older
                ii. Three months or more for any patient with history of fragility
                iii. Three months or more for postmenopausal female
                iv. Twelve months or more
    B. *Failure of, inability to tolerate, or contraindication to oral or intravenous bisphosphonates*
    C. *Risk factors for fracture, as indicated by **1 or more** of the following:*
        1. *Alcohol intake of 3 or more drinks per day*
        2. *BMI less than 20*
        3. *Corticosteroid use of more than 6 months' duration*
        4. *Current or past history of cigarette smoking*
        5. *Parental hip fracture*
        6. *Personal history of fragility or osteoporotic fracture after age 50 years*

III. Denosumab Injection (Prolia or Xgeva) are considered medically necessary when the **ONE** of the following criteria is met:
    A. Giant cell tumor of bone in adult or skeletally mature adolescent, as indicated by **ONE** of the following:
        1. *Recurrent disease*
        2. *Unresectable disease, or located where planned surgery is likely to result in severe morbidity*
    B. Hypercalcemia of malignancy, as indicated by **ALL** of the following:
        1. *Hypercalcemia due to current malignancy*
        2. *Serum calcium of 12.5 mg/dL (3.1 mmol/L) or greater, after correction for serum albumin*
        3. *Refractory to bisphosphonate therapy*
    C. Prevention of osteoporosis, as indicated by **1 or more** of the following:
        1. Prevention of bone loss in female with breast cancer, as indicated by **ALL** of the following
            a. *Patient receiving adjuvant therapy with aromatase inhibitor*

b. *Risk factors for fracture, as indicated by **2 or more** of the following:*
    i. *Age older than 65 years*
    ii. *Alcohol intake of 3 or more drinks per day*
    iii. *Annual decrease of bone mineral density of 10% or more*
    iv. *BMI less than 20*
    v. *Bone mineral density T-score less than minus 1.5*
    vi. *Corticosteroid use of more than 6 months' duration*
    vii. *Current or past history of cigarette smoking*
    viii. *Parental hip fracture*
    ix. *Personal history of fragility fracture after age 50 years*

2. Prevention of bone loss in male with prostate cancer, as indicated by **ALL** of the following:
    a. *Age 70 years or older*
    b. *Patient receiving androgen deprivation therapy*
    c. *Risk factors for fracture, as indicated by **2 or more** of the following:*
        i. *Alcohol intake of 3 or more drinks per day*
        ii. *Corticosteroid use of more than 6 months' duration*
        iii. *Current or past history of cigarette smoking*
        iv. *Femoral neck, lumbar spine, or total hip bone mineral density T-score less than minus 1.0*
        v. *Parental hip fracture*
        vi. *Personal history of fragility or osteoporotic fracture after age 50 years*

D. Osteoporosis and need for treatment in patient at high risk for fracture, as indicated by **ALL** of the following:
1. Documented osteoporosis in male or postmenopausal female, as indicated by **1 or more** of the following
    a. *Femoral neck, lumbar spine, or total hip bone mineral density T-score of less than minus 2.5*
    b. *History of osteoporotic fracture*
2. Inability to tolerate or contraindication to other available osteoporosis therapy, including **1 or more** of the following:
    a. *Calcitonin*
    b. *Intravenous bisphosphonate (eg, ibandronate, zoledronic acid)*
    c. *Oral bisphosphonate (eg, alendronate, risedronate, ibandronate)*
    d. *Raloxifene*
    e. *Teriparatide*

E. Prevention or treatment of skeletal-related events from cancer metastatic to bone, as indicated by **ALL** of the following:
1. *Standard antineoplastic therapy continues*
2. *Osteolytic bone lesions or bone metastases from solid tumors, including **1 or more** of the following:*
    a. *Breast cancer*
    b. *Prostate cancer*
    c. *Other solid tumors (eg, lung or renal cancer)*

Note: Documented diagnosis must be confirmed by contemporaneous portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

Refer to the product package insert for dosing, administration and safety guidelines.

ALL other uses of Calcium Regulators are considered experimental/investigational and therefore, will follow CareSource's Medical Necessity - Off-Label, Approved Orphan and Compassionate Use Drugs.

CONDITIONS OF COVERAGE

HCPCS	J1740	Boniva Injection
	J3489	Reclast Infusion, Zometa, Zoledronic Acid
	J3110	Forteo Injection
	J0897	Xgeva, Prolia Injection
CPT		

PLACE OF SERVICE
Office, Outpatient, Home
Note: CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

AUTHORIZATION PERIOD
Approved initial authorizations are valid for up to **1 (one)** year (if applicable). Continued treatment may be considered when the member has shown biological response to treatment. **ALL** authorizations are subject to continued eligibility.

C. REVIEW/REVISION HISTORY

Date Issued:	06/15/2011
Date Reviewed:	06/15/2011, 08/01/2013, 05/16/2014
Date Revised:	12/15/2015 – Revisions to criteria and add Forteo
	03/15/2015 – Placed into new template
	11/17/2015 – Revisions to indications and added limitations of use
	07/13/16 – Revisions to include changes to format

D. REFERENCES

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This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent Medical Review: 05/19/2011