MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
06/15/2011	12/16/2015	12/16/2014

Policy Name	Policy Number
Calcium Regulators (Reclast, Zometa, Boniva, Prolia, Forteo, Xgeva)	**SRx-0021**

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

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 Step-Therapy. 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 **zoledronic acid (Reclast, Zometa) denosumab (Prolia)**, or **ibandronate sodium (Boniva), teriparatide (Forteo)** and consider its use as medically necessary when **ALL** of the following criteria have been met for:

- Prevention/treatment of osteoporosis with high risk of fracture (Prolia)
- Prevention/treatment of osteoporosis (Reclast, Boniva, Forteo)
- Glucocorticoid induced osteoporosis (Reclast & Forteo)
- Paget's disease of bone (Reclast only)
- Hypercalcemia of malignancy (Zometa only)
- Bone Metastases (Zometa, Xgeva)
- Multiple Myeloma (Zometa only)
- Reduction of Bone Loss in Men Receiving Androgen Deprivation Therapy for Prostate Cancer (Prolia only)
- Reduction of Bone Loss in Women being Treated for Breast Cancer (Prolia only)
- Skeletal Osteolytic or Osteoblastic Metastases from Solid Tumors (Xgeva only)
- Risk for fracture

Treatment of osteoporosis in postmenopausal women

Zoledronic acid (Reclast), teriparatide (Forteo), and ibandronate sodium (Boniva) are indicated for treatment of osteoporosis in postmenopausal women.

Prior Authorization Criteria for Forteo when ALL of the following are present:

- Documented diagnosis of osteoporosis by **ONE OR MORE** of the following:
  - Confirmed by a bone mineral density test (BMD) (e.g. DEXA scan)
  - T score of their bone mineral density of minus 2.5 or less
  - Previous osteoporotic vertebral compression fracture, or fracture of the hip or distal radius resulting from fragility.
- Failure of at least one of the oral bisphosphonates or Selective Estrogen Receptor Modulators (SERMs) after a 12 month trial:
  - alendronate (Fosamax)
  - Actonel
  - Boniva
  - Tamoxifen
  - Evista
  - Fariston

  OR
  - Unable to tolerate or has a medical contraindication of oral therapy
    - Inability to swallow
    - Inability to remain in an upright position for one hour post administration
    - Upper GI disease (such as reflux, GERD, esophageal stricture)
- No active Paget disease of bone
- No history of skeletal irradiation
- No hypercalcemia
- No skeletal malignancy or metastasis

Prior Authorization Criteria for Reclast and Boniva when ALL of the following are present:

- Documentation meeting the criteria above for Forteo
- **AND** Failure of 12 months of Forteo therapy or intolerance to Forteo therapy.

Treatment of osteoporosis in men (Reclast, Forteo and Boniva
Zoledronic acid (Reclast), Teriparatide (Forteo), and ibandronate sodium (Boniva) are indicated for treatment of osteoporosis in men.

Prior Authorization Criteria for Reclast and Boniva when ALL of the following are present:
- Documented diagnosis of osteoporosis **by ONE OR MORE of the following:**
  - Confirmed by a bone mineral density test (BMD) (e.g. DEXA scan)
  - T score of their bone mineral density of minus 2.5 or less **or**
  - Previous osteoporotic vertebral compression fracture, or fracture of the hip or distal radius resulting from fragility
  - Osteoporosis secondary to hypogonadism and failure of or intolerance to testosterone
- Failure of at least one of the oral bisphosphonates or SERMs after a 12 month trial:
  - alendronate (Fosamax)
  - Actonel
  - Boniva
  - Tamoxifen
  - Evista
  - Fariston

    OR
  - Unable to tolerate or has a medical contraindication of oral therapy
    - Inability to swallow
    - Inability to remain in an upright position for one hour post administration
    - Upper GI disease (such as reflux, GERD, esophageal stricture)

Prior Authorization Criteria for Teriparatide (Forteo):
- Male with hypogonadal or primary osteoporosis, as indicated by **ONE OR MORE** of the following:
  - Femoral neck, spine, or total hip bone mineral density T-score minus 2.5 or less
  - Hip or vertebral fragility (ie, low-trauma) fracture in patient older than 50 years

Prevention of osteoporosis in postmenopausal women
Zoledronic acid (Reclast), teriparatide (Forteo), and ibandronate sodium (Boniva) are indicated for prevention of osteoporosis in postmenopausal women.

Prior Authorization Criteria when ALL of the following are present:
- Documented diagnosis of osteopenia
  - Confirmed by a bone mineral density test (BMD) (e.g. DEXA scan with T-score as listed below)
  - T score of their bone mineral density between and minus 1 to minus 2.5
- Risk factor(s) for fractures as indicated by **ONE OR MORE** of the following:
  - Alcohol intake of 3 or more drinks per day
  - BMI less than 20
  - Corticosteroid use of more than 6 months' duration
  - Current or past history of cigarette smoking
  - Parental hip fracture
  - Personal history of fragility or osteoporotic fracture after age 50 years
- Failure of at least one of the oral bisphosphonates after a 12 month trial:
  - alendronate (Fosamax)
  - Actonel
  - Boniva (oral)

    OR

- Unable to tolerate or has a medical contraindication of oral bisphosphonates
  - Inability to swallow
  - Inability to remain in an upright position for one hour post administration
  - Upper GI disease (such as reflux, GERD, esophageal stricture)
- No active Paget disease of bone
- No history of skeletal irradiation
- No hypercalcemia
- No skeletal malignancy or metastasis

Prevention of osteoporosis in men

Zoledronic acid (Reclast), ibandronate sodium (Boniva), and teriparatide (Forteo) are indicated for treatment to increase bone mass in men with osteoporosis.

Prior Authorization Criteria for Forteo when ALL of the following are present:

- Documented diagnosis of osteopenia as indicated by **ONE OR MORE** of the following:
  - Confirmed by a bone mineral density test (BMD) (e.g. DEXA scan)
  - T score of their bone mineral density of minus 2.5 or less
  - Previous osteoporotic vertebral compression fracture, or fracture of the hip or distal radius resulting from fragility
- Failure of at least one of the oral bisphosphonates after a 12 month trial:
  - alendronate (Fosamax)
  - Actonel
  - Ibandronate (Boniva)

    OR
  - Unable to tolerate or has a medical contraindication of oral bisphosphonates
    - Inability to swallow
    - Inability to remain in an upright position for one hour post administration
    - Upper GI disease (such as reflux, GERD, esophageal stricture)
- Risk factors for fracture, as indicated by **TWO OR MORE** of the following:
  - Alcohol intake of 3 or more drinks per day
  - BMI less than 20
  - Corticosteroid use of more than 6 months' duration
  - Current or past history of cigarette smoking
  - Parental hip fracture
  - Personal history of fragility or osteoporotic fracture after age 50 years
- No active Paget disease of bone
- No history of skeletal irradiation
- No hypercalcemia
- No skeletal malignancy or metastasis

Prior Authorization Criteria for Reclast and Boniva when ALL of the following are present:

- Documentation meeting the criteria above for Forteo

  AND Failure of 12 months of Forteo therapy or intolerance to Forteo therapy
- Documented diagnosis of prostate cancer and receiving androgen deprivation therapy
- Risk factors for fracture, as indicated by **TWO OR MORE** of the following:
  - Alcohol intake of 3 or more drinks per day
  - Bone mineral density T-score of minus 1.0 or less
  - Corticosteroid use of more than 6 months' duration
  - Current or past history of cigarette smoking
  - Parental hip fracture or personal history of fragility or osteoporotic fracture

Glucocorticoid induced osteoporosis

Zoledronic acid (Reclast) and teriparatide (Forteo) are indicated for the treatment and prevention of glucocorticoid-induced osteoporosis in men and women who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 5 mg or greater of prednisone and who are expected to remain on glucocorticoids for at least 3 months.

Prior Authorization Criteria when ALL of the following are present:

- Documented diagnosis of glucocorticoid-induced osteoporosis as indicated by **ONE OR MORE** of the following:
  - Confirmed by a bone mineral density test (BMD) (e.g., DEXA scan)
  - T score of their bone mineral density of minus 2.5 or less
  - History fracture(s).
- History of sustained systemic glucocorticoid therapy in a daily dosage equivalent to 7.5 mg or greater of Prednisone and who are expected to remain on glucocorticoids for at least 3 months.
- Failure of at least one of the oral bisphosphonates after a 12 month trial:
  - alendronate (Fosamax)
  - Actonel
  - Ibandronate (Boniva)

    OR
  - Unable to tolerate or has a medical contraindication of oral bisphosphonates
    - Inability to swallow
    - Inability to remain in an upright position for one hour post administration
    - Upper GI disease (such as reflux, GERD, esophageal stricture)
- No active Paget disease of bone
- No history of skeletal irradiation
- No hypercalcemia
- No skeletal malignancy or metastasis

Paget's disease of bone (Reclast and Boniva only)

Zoledronic acid (Reclast) and ibandronate sodium (Boniva) are indicated for treatment of Paget's disease of bone in men and women. Treatment is indicated in patients with Paget's disease of bone with elevations in serum alkaline phosphatase of two times or higher than the upper limit of the age-specific normal reference range, or those who are symptomatic, or those at risk for complications from their disease.

Prior Authorization Criteria when ALL of the following are present:

- Documented diagnosis of Paget's disease as indicated by the following:
  - Confirmed by Serum alkaline phosphatase elevations are two times or higher than the upper limit of the age-specific normal reference range
- Prescribed by an endocrinologist or under the recommendation of an endocrinologist
- Patient not pregnant
- Failure of at least one of the oral bisphosphonates after a 12 month trial:
  - etidronate (Didronel)
  - alendronate (Fosamax)
  - Actonel

    OR
- Unable to tolerate or has a medical contraindication of oral bisphosphonates
  - Inability to swallow
  - Inability to remain in an upright position for one hour post administration
  - Upper GI disease (such as reflux, GERD, esophageal stricture)

Skeletal metastases from cancer

Zoledronic acid (Reclast), and ibandronate sodium (Boniva) are indicated for treatment of skeletal metastases from cancer for men and women. It is given in conjunction with standard antineoplastic therapy.

Prior Authorization Criteria when ALL of the following are present:

- Documented diagnosis of osteolytic bone lesions or metastases as indicated by **ONE OR MORE** of the following:
  - Breast cancer
  - Multiple myeloma (Reclast and Boniva only)
  - Prostate cancer, if progression occurred after androgen deprivation therapy
  - Other solid tumors (eg, lung cancer, renal cancer)
- Prescribed by an oncologist/hematologist or under recommendation of oncologist/hematologist
- Patient not pregnant

Hypercalcemia of malignancy

Zoledronic acid (Reclast), Zoledronic acid (Zometa), and ibandronate sodium (Boniva) are indicated in the treatment of hypercalcemia of malignancy for patients with multiple myeloma or documented bone metastases from solid tumors. It is given in conjunction with standard antineoplastic therapy. Treatment for patients with prostate cancer is indicated only after documented progression of disease following treatment with at least one hormonal therapy.

Prior Authorization Criteria when ALL of the following are present:

- Documented diagnosis of hypercalcemia from a malignant condition as indicated by **ALL** of the following:
  - Confirmed by lab results
  - Albumin-corrected serum calcium ~~of~~ 12 mg/dL or greater
- Prescribed by an oncologist/hematologist or under recommendation of oncologist/hematologist
- Patient not pregnant
- Vigorous saline hydration, with urine output of 2 L per day or greater, being maintained

Treatment of Men & Postmenopausal Women with Osteoporosis at High Risk for Fracture (Prolia)

Denosumab (Prolia) is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture.

Prior Authorization Criteria when ALL of the following are present:

- Documented osteoporosis, as indicated by **ONE OR MORE** of the following:
  - Lumbar spine bone mineral density T score of less than -2.5
  - Total hip bone mineral density T score of less than -2.5
  - Femoral neck bone mineral density T score of less than -2.5
  - History of osteoporotic fracture
- Failure of or inability to tolerate other available osteoporosis therapy, including **1 or more** of the following
  - Oral bisphosphonate (e.g., alendronate, risedronate, ibandronate)
  - Intravenous bisphosphonate (e.g., ibandronate, zoledronic acid)
  - Raloxifene
  - Calcitonin
  - Teriparatide

- No hypocalcemia at time of administration

Reduction of Bone Loss in Men Receiving Androgen Deprivation Therapy for Prostate Cancer (Prolia)
Denosumab (Prolia) is indicated for the treatment of prostate cancer.

Prior Authorization Criteria when ALL of the following are present:
- Non-metastatic disease
- Patient receiving androgen deprivation therapy
- High risk for fracture, as indicated by **1 or more** of the following:
  - Lumbar spine bone mineral density T score less than minus1.0
  - Total hip bone mineral density T score less than minus1.0
  - Femoral neck bone mineral density T score less than minus1.0
  - History of osteoporotic fracture
- No hypocalcemia at time of administration

Reduction of Bone Loss in Women Being Treated for Breast Cancer (Prolia)
Denosumab (Prolia) is indicated for the treatment of breast cancer.

Prior Authorization Criteria when ALL of the following are present:
- Patient receiving adjuvant therapy with aromatase inhibitor
- High risk for fracture, as indicated by **1 or more** of the following:
  - Lumbar spine bone mineral density T score less than -1.0
  - Total hip bone mineral density T score less than -1.0
  - Femoral neck bone mineral density T score less than -1.0
  - History of osteoporotic fracture
- No hypocalcemia at time of administration
- Patient is not pregnant

Skeletal Osteolytic or Osteoblastic Metastases from Solid Tumors (Xgeva)
Denosumab (Xgeva) is indicated for the treatment of skeletal metastases from cancer.

Prior Authorization Criteria when ALL of the following are present:
- Current osteolytic or osteoblastic bone lesions or metastases from solid tumors (e.g., breast, prostate, and lung cancers)
- Standard antineoplastic therapy continues

Risk for fracture
Teriparatide (Forteo) is indicated for the prevention of fracture in adult men and women (18 years and older) who are at high risk for fracture.

Prior Authorization Criteria:
- Must include **1 or more** of the following:
  - Bone mineral density T score less than minus 3.0
  - Family history of parental hip fracture
  - History of fragility (low trauma) fracture
  - Strong family history of osteoporosis

  AND
- Failure of at least one of the oral bisphosphonates after a 12 month trial:
  - alendronate (Fosamax)
  - Actonel

- Ibandronate (Boniva)
  OR
- Unable to tolerate or has a medical contraindication of oral bisphosphonates
  - Inability to swallow
  - Inability to remain in an upright position for one hour post administration
  - Upper GI disease (such as reflux, GERD, esophageal stricture)

Bone metastases from solid tumors (Xgeva)
Denosumab (Xgeva) is indicated for the following:
- Prevention of skeletal-related events in patients with bone metastases from solid tumors
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity

Prior Authorization Criteria when ALL of the following are present:
- Current metastases from solid tumors (e.g., breast, prostate, and lung cancers)
- Standard antineoplastic therapy continues

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.

All other uses of Calcium Regulators are considered experimental/investigational and therefore, will follow CareSource's off-label policy.

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

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

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

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 inject able medications in various setting, 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 3 months (if applicable). Continued treatment may be considered when the member has shown biological response to treatment. **ALL** authorizations are subject to continued eligibility.

E. REVIEW/REVISION HISTORY

Date Issued:	06/15/2011
Date Reviewed:	06/15/2011, 08/01/2013, 05/16/2014, 12/16/2014
Date Revised:	08/01/2013 12/16/2014 – Revisions to criteria and add Forteo. 03/10/2015 – Placed into new template.

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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.