

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE



POLICY:	Osteoporosis	P&T DATE:	12/10/2024
THERAPEUTIC CLASS:	Endocrine Disorders	REVIEW HISTORY:	1/24, 11/22, 9/21, 9/20,
LOB AFFECTED:	MCL	(MONTH/YEAR)	12/16, 2/15, 5/13, 9/12, 5/11

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the Health Plan of San Joaquin/Mountain Valley Health Plan (Health Plan) Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit <https://med-calrx.dhcs.ca.gov/home/> for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.

All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

OVERVIEW

The goal of osteoporosis treatment is to prevent future complications, such as fractures, from occurring. Treatment of fractures means greater medical and personal burden for elderly patients. As the predicted cost of care for fractures is expected to rise to \$25.3 billion by 2025¹, the following measures to reduce the risk of fractures would be advantageous for everyone. The National Osteoporosis Foundation (NOF) provides recommendations for the overall treatment of osteoporosis as well as preventative measures to delay progression towards osteoporosis itself. This review will examine the treatment guidelines for osteoporosis, currently available agents for osteoporosis, and their coverage criteria.

Table 1: Osteoporosis Agents

CPT Code	Drug	Available Strengths	Pharmacy Benefit	Medical Benefit
Bisphosphonates				
--	Alendronate (Fosamax)	Tablets: 5mg, 10mg, 35mg, 40mg, 70mg Solution: 70 mg/75 mL	Yes	No
J1740	Ibandronate (Boniva)	Tablets: 150mg IV infusion: 1 mg/mL	Yes, for tablets	Yes, for vials (PA)
--	Risedronate (Actonel)	Tablets: 5mg, 30mg, 35mg, 150mg	Yes	No
--	Risedronate DR (Atelvia)	Tablets: 35mg	Yes	No
J3489	Zoledronic Acid (Reclast)	IV infusion: 5 mg/100 mL, 4 mg/5 mL	Yes	Yes (QL)
Estrogen agonist/antagonists (previously called SERMs)				
--	Raloxifene (Evista)	Tablets: 60mg	Yes	No
Calcitonin				
J0630	Calcitonin (Miacalcin)	Nasal solution: 200 units/actuation Injection solution: 200 units/mL	Yes, for nasal solution	Yes, for vials (DL)
Tissue-Selective Estrogen Complex				

--	Conjugated estrogens/bazedoxifene (Duavee)	Tablets: 20mg/0.45mg	Yes	No
Parathyroid Hormone Analogs				
J3110	Teriparatide (Forteo)	Pen-injector solution: 620mcg/mL	Yes	No
--	Abaloparatide (Tymlos)	Pen-injection solution: 3120 mcg/1.56 mL	Yes	No
RANKL Inhibitors				
J0897	Denosumab (Prolia)	Prefilled syringe solution: 60mg/mL	Yes	Yes (PA)
Sclerostin Inhibitor				
J3111	Romosozumab (Evenity)	Prefilled syringe solution: 10mg/1.17mL	Yes	Yes (PA)

PA=prior authorization, QL=quantity limit, DL=diagnosis limit

Clinical Justification:

World Health Organization Criteria for Classification of Osteopenia and Osteoporosis

Category	T-score
Normal	-1.0 or above
Low bone mass (osteopenia)	Between -1 and -2.5
Osteoporosis	-2.5 or below
Severe Osteoporosis	-2.5 and below with history of a fracture

The NOF recommends that pharmacologic therapy should be reserved for postmenopausal women and men aged 50 years or older who represent with the following 3 categories:

- History of hip or vertebral fracture (vertebral fractures may be clinical or asymptomatic)
- T score of -2.5 or less at the femoral neck, or spine after appropriate evaluation to exclude secondary causes
- Low bone mass (T score between -1.0 and -2.5 at the femoral neck or spine) and a 10 year probability of a hip fracture of 3% or higher or a 10 year risk of a major osteoporosis-related fracture of 20% or greater based on the US adapted WHO absolute fracture risk model (Fracture Risk Algorithm: FRAX)

Bisphosphonates in combination with calcium and vitamin D supplementation are recognized by the National Osteoporosis Foundation Guidelines as a cost-effective first-line therapy option for osteoporosis.

Many osteoporosis agents are covered by Medi-Cal Rx via the pharmacy benefit. These agents include Alendronate, Risedronate, Calcitonin, Teriparatide, Abaloparatide, and more.

Prolia and Evenity are reserved for treatment failure or intolerance to bisphosphonates as they are less cost-effective. Bisphosphonates such as Zoledronate, Alendronate, and Risedronate are also recommended by the 2020 AACE/ACE Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis for very high risk patients or patients with prior fractures.¹³ For patients who cannot tolerate at least two bisphosphonates, the health plan's criteria will allow for bypass of treatment failure to a bisphosphonate. An exception is also made for Evenity use in patients at very high risk of fracture. According to the Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society, Evenity is an anabolic agent and results in larger, faster gains in bone marrow density and better protection from fractures than bisphosphonates. Bone mineral density gains, particularly in the hip, are greater when the anabolic drug

is administered before the antiremodeling drug compared with the opposite sequence. The best candidates are women at very high risk of fracture.¹⁹

Duration of therapy needs to be individualized. The recommendation for 5 years of therapy may be appropriate for some, but not for other patients. Drug holidays are not recommended for those on Prolia since the protection from vertebral fracture may be lost within 3-18 months after discontinuation.⁷

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the Health Plan Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, Health Plan will make the determination based on Medical Necessity as described in Health Plan Medical Review Guidelines (UM06).

Bisphosphonates

Ibandronate (Boniva), Zoledronate (Reclast)

- ☐ **Coverage Criteria:**
 - Boniva (Ibandronate Sodium) is reserved for treatment failure after an adequate trial or intolerance to alendronate.
- ☐ **Limits:**
 - Zoledronate: Auth not required but restricted to 5 mg per 365 days.
- ☐ **Required Information for Approval:**
 - Ibandronate: Fill history or documentation of intolerance to alendronate.

Receptor Activator of Nuclear Kappa-B Ligand Inhibitor

Denosumab (Prolia)

- ☐ **Coverage Criteria:** Prolia is reserved for treatment failure to bisphosphonate with calcium therapy, defined as progression of bone loss or fracture occurring while on therapy OR intolerance to 2 formulary bisphosphonates.
- ☐ **Limits:** Limited to 1 fill per 180 days.
- ☐ **Required Information for Approval:**
 - Clinical evidence of osteoporosis via a documented t-score <-2.5
 - Treatment failure to 1 year of bisphosphonate with calcium treatment OR failure/intolerance to 2 formulary bisphosphonates

Sclerostin Inhibitor

Romosozumab (Evenity)

- ☐ **Coverage Criteria:** Evenity is reserved for either 1 or 2:
 - 1) Treatment failure to bisphosphonate with calcium therapy, defined as progression of bone loss or fracture occurring while on therapy OR intolerance to 2 bisphosphonates
 - 2) Treatment of very high-risk patients defined as having one of the following:
 - History of multiple fractures
 - Recent fracture within the past 12 months
 - Fracture or progression of bone loss while on approved osteoporosis therapy
 - Fracture while on drugs causing skeletal harm such as long-term glucocorticoids
 - Very low T-score <-3.0
 - High risk for falls or history of injurious falls
 - FRAX >30% for major osteoporosis fracture or >4.5% for hip fracture
 - Severe vertebral fracture (>40% loss of vertebral height)
- ☐ **Limits:** 2 pens (1.17ml each) per 30 days. Limited to 12 total months of treatment.
- ☐ **Required Information for Approval:**

- Treatment failure to one bisphosphonate with calcium treatment OR failure/intolerance to 2 bisphosphonates OR
- Documentation of osteoporosis with very high risk of fracture
- No previous history of heart attack or stroke within one year of initiating therapy

Calcitonin

Calcitonin (Miacalcin)

- ❑ **Coverage Criteria:** N/A
- ❑ **Limits:** Limited to hypercalcemia use only.
- ❑ **Required Information for Approval:** Hypercalcemia diagnosis code.
- ❑ **Other Notes:** For osteoporosis or Paget's Disease, Calcitonin must be billed via the pharmacy benefit.

REFERENCES

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20. Vertebral fractures. IOF International Osteoporosis Foundation. Accessed November 27, 2024.
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REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Formulary Realignment 5-11.xlsx	05/2011	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment PT 9-18-12.xlsx	09/2012	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment PT 5-21-13.xlsx	05/2013	Jonathan Szkotak, PharmD BCACP
Update to Policy	Osteoporosis Class Review 2-17-15.xlsx	02/2015	Jonathan Szkotak, PharmD BCACP
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Osteoporosis 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Osteoporosis 2018-9.docx	9/2018	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Osteoporosis 2019-9.docx	9/2019	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Osteoporosis 2020-9.docx	9/2020	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Osteoporosis 2021-9.docx	9/2021	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Osteoporosis 2022-11.docx	11/2022	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Osteoporosis 2024-1.docx	1/2024	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Osteoporosis 2024-12.docx	12/2024	Matthew Garrett, PharmD

Note: All changes are approved by the Health Plan P&T Committee before incorporation into the utilization policy.