MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Health Plan of San Joaquin

POLICY:	Osteoporosis	**P&T DATE:**	9/15/2020
THERAPEUTIC CLASS:	Endocrine Disorders	**REVIEW HISTORY:** (MONTH/YEAR)	12/16, 2/15, 5/13, 9/12, 5/11
LOB AFFECTED:	MCL		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

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 2025[1], 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 *(Current as of 9/2020)*

Class	Drug	Available Strengths	Form. Status	Restriction (Blank = No restriction)	Cost Per Rx¥
Bisphosphonates	Alendronate (Fosamax, Binosto is NF) *Tablets, Solution*	Tablets: 5mg, 10mg, 35mg, 40mg, 70mg Solution: 70 mg/75 mL	F, QL	Restricted to 4 tablets per month (35mg and 70mg) or 30 tablets per month (5mg, 10mg and 40mg).	$12.50
	Ibandronate (Boniva) *Tablets, IV infusion is NF*	Tablets: 150mg IV infusion: 1 mg/mL	F, QL, ST	Step therapy to an adequate trial or intolerance to Alendronate. Restricted to 1 tablet per month.	$6.25
	Risedronate (Actonel*)*	Tablets: 5mg, 30mg, 35mg, 150mg	F, QL, PA	Step therapy to an adequate trial or intolerance to Alendronate; restricted to 1 tablet per month (150mg), 4 tablets per month (35mg IR), or 30 tablets per month (5mg). Risedronate 30mg tablets are reserved for treatment failure or intolerance to Alendronate for use in Paget's Disease; restricted to 30 tablets per month.	$28.45
	Risedronate DR (Atelvia)	Tablets: 35mg	NF		--
	Zoledronic Acid (Reclast) *IV infusion*	5 mg/100 mL, 4 mg/5 mL	F, QL	1 fill per 365 days.	$15.75
Estrogen agonist/antagonist (previously called SERMs)	Raloxifene (Evista) *Tablets*	60 mg	NF		$16.45
Calcitonin	Calcitonin (Miacalcin) *Intranasal*	200 units/actuation	F, ST	Reserved as last-line therapy for treatment	$56.98

				failure/intolerance to all other formulary agents.	
Tissue-Selective Estrogen Complex	Conjugated estrogens/bazedoxifene (Duavee) *Tablets*	20 mg/0.45 mg	NF		--
Parathyroid Hormone Analogs	Teriparatide (Forteo) *SQ injection*	600 mcg/2.4 mL	F, PA, SP, QL	Reserved for treatment of osteoporosis as evidenced by documented t-score <-2.5 in patients with treatment failure to or intolerance to Abaloparatide. 1 pen per 28 days.	$3,524.16
	Abaloparatide (Tymlos) *SQ injection*	3120 mcg/1.56 ml	F, PA, SP, QL	Reserved for treatment of osteoporosis as evidenced by t-score <-2.5 in patients with treatment failure to one bisphosphonate or intolerance to two bisphosphonates OR patients with t-score ≤-3.0 with back pain. 1 pen per 30 days.	$1,946.97
RANKL inhibitor	Denosumab (Prolia) *SQ injection*	60 mg/mL	F, PA, SP. QL	Reserved for treatment of osteoporosis as evidenced by t-score <-2.5 in patients with treatment failure to one bisphosphonate or intolerance to two bisphosphonates. 1 fill per 180 days.	$1,534.55
Sclerostin Inhibitor	Romosozumab (Evenity) *SQ injection*	10mg mg/1.17 ml	F, PA, SP, QL	Reserved for treatment of osteoporosis as evidenced by t-score <-2.5 in patients with treatment failure to one bisphosphonate or intolerance to two bisphosphonates. 2 pens per 30 days.	$2,189.98

F = Formulary, QL = Quantity Limit, ST = Step therapy, PA = Prior Authorization required. SP = Specialty Pharmacy
RANKL = Receptor Activator of Nuclear Factor kappa-B Ligand

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 first-line therapy for osteoporosis. In regards to all other treatment modalities, very little direction is provided.

Miacalcin has yet to prove its efficacy in decreasing fracture risk or incidence, however, as it is a recommended agent that has not proven to be harmful or have any significant risks, it is available as a last line agent after all other options have failed or are contraindicated.

Due to uncertainty in its benefits and a higher risk of thromboembolism, Duavee is not on formulary.

Prolia has been shown to have comparable health benefits to alendronate and similar effectiveness to Forteo. However, Prolia is only dosed every 6 months, whereas Forteo is dosed daily. Along with the possible benefit of improved patient adherence to Prolia, Prolia is also more cost-effective, making it the better alternative to treatment failure of bisphosphonate therapy.

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]

Triage:

- ***Appropriate diagnosis (labs/clinical documentation of osteoporosis)***
- ***Past medication history related to treating osteoporosis***
- ***History of osteoporosis medication intolerances***

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 HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Bisphosphonates

Alendronate (Fosamax), Ibandronate (Boniva), Risedronate (Actonel), Zoledronate (Reclast)

- ❒ **Coverage Criteria:**
  - Boniva (Ibandronate Sodium) is step therapy to an adequate trial or intolerance to alendronate.
  - Actonel (Risedronate) 150mg, 35mg IR, and 5mg tablets are step therapy to an adequate trial or intolerance to alendronate.
  - Actonel (Risedronate) 30mg tablets are reserved for treatment failure or intolerance to Alendronate for use in Paget's Disease.
- ❒ **Limits:**
  - Alendronate:
    - Alendronate 35mg and 70 mg is restricted to 4 tablets per month.
    - Alendronate 5mg, 10mg, and 40mg is restricted to 30 tablets per month.
  - Ibandronate: Restricted to 1 tablet per month.
  - Risedronate:
    - Risedronate 150mg is restricted to 1 tablet per month.
    - Risedronate 35mg IR is restricted to 4 tablets per month.
    - Risedronate 5mg is restricted to 30 tablets per month.
    - Risedronate 30mg is restricted to 30 tablets per month.
  - Zoledronate: Restricted to 1 fill per 365 days.
- ❒ **Required Information for Approval:**

- Ibandronate: Fill history or documentation of intolerance to alendronate.
- Risedronate 150mg, 35mg IR, 5mg: Fill history or documentation of intolerance to alendronate.
- Risedronate 30mg: Fill history or documentation of intolerance to alendronate and Paget's Disease.
- Zoledronate: Documentation of inability to swallow tablets.

Calcitonin

Calcitonin (Miacalcin)

- ❒ **Coverage Criteria:** Calcitonin nasal spray is reserved as last-line therapy for treatment failure/intolerance to ALL other formulary agents.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Fill history or documentation of treatment failure/intolerance to ALL other formulary agents

Parathyroid Hormone

Abaloparatide (Tymlos)

- ❒ **Coverage Criteria:** Abaloparatide is reserved for any of the following: [1] treatment failure to bisphosphonate with calcium therapy, defined as progression of bone loss or fracture occurring while on therapy; [2] intolerance to 2 formulary bisphosphonates; or [3] patients with a T-score of the spine of less than or equal to -3.0 with back pain.
- ❒ **Limits:** 1 pen (1.56 ml) per 28 days. Restricted to specialty pharmacy. Limited to 24 total months of treatment.
- ❒ **Required Information for Approval:**
  - Clinical evidence of osteoporosis via a documented t-score <-2.5
  - Treatment failure to one bisphosphonate with calcium treatment OR failure/intolerance to 2 formulary bisphosphonates

Teriparatide (Bonsity)

- ❒ **Coverage Criteria:** Teriparatide is for treatment of osteoporosis as evidenced by documented T-score <-2.5 in patients with treatment failure or intolerance to Abaloparatide.
- ❒ **Limits:** 1 pen (2.4ml) per 28 days. Restricted to specialty pharmacy. Limited to 24 total months of treatment.
- ❒ **Required Information for Approval:**
  - Clinical evidence of osteoporosis via a documented t-score <-2.5
  - Treatment failure or intolerance to Abaloparatide

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. Restricted to specialty pharmacy.
- ❒ **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 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:** 2 pens (1.17ml each) per 30 days. Restricted to specialty pharmacy. Limited to 12 total months of treatment.
- ❒ **Required Information for Approval:**
  - Clinical evidence of osteoporosis via documented t-score < -2.5
  - Treatment failure to one bisphosphonate with calcium treatment OR failure/intolerance to 2 formulary bisphosphonates
  - No previous history of heart attack or stroke

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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

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