

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE



POLICY:	Osteoporosis	P&T DATE:	12/09/2025
THERAPEUTIC CLASS:	Endocrine Disorders	REVIEW HISTORY:	12/25, 1/24, 11/22, 9/21,
LOB AFFECTED:	MCL	(MONTH/YEAR)	9/20, 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.

This coverage policy is updated on an annual basis. For more recent or up-to-date criteria, reference the Medi-Cal Provider Manual and/or the Medicare National Coverage Determination/Local Coverage Determination (NCD/LCD) for specific criteria. If the Medi-Cal Provider Manual and/or the Medicare NCD/LCD do not have medical necessity criteria, please refer to the "Evaluation Criteria" section in this policy for specific criteria. It is also important to reference the Medicare Benefit Manuals - Chapter 15 and Chapter 16 - when determining benefit coverage and criteria for review of physician administered drugs on the Medicare benefit.

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 measures to reduce the risk of fractures would be advantageous for everyone. 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 (<https://www.sciencedirect.com/science/article/pii/S1530891X20428277>) 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 (https://journals.lww.com/menopausejournal/abstract/2021/09000/management_of_osteoporosis_in_postmenopausal.3.aspx), 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

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.
 - Zoledronate: Authorization not required
- Limits:** N/A
- 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

1. Office of the Surgeon General (US). *Bone Health and Osteoporosis: A Report of the Surgeon General*. Rockville (MD): Office of the Surgeon General (US); 2004.
2. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014.
3. Tymlos [package insert]. Radius Health, Incorporated. Waltham, Massachusetts. April 2017.
4. Hattersley G, Dean T, Corbin BA, et al. Binding Selectivity of Abaloparatide for PTH-Type-1-Receptor Conformations and Effects on Downstream Signaling. *Endocrinology* 2016; 157:141-149.
5. Miller P, Hattersley, G, et al. Effects of Abaloparatide vs Placebo on New Vertebral Fractures in Postmenopausal Women with Osteoporosis A Randomized Control Trial. *JAMA*. 2016;316(7):722-733
6. US Preventive Services Task Force. Screening for osteoporosis to prevent fractures: US Preventative Services Task Force recommendation statement. *JAMA* 2018;319(24):2521-2531.
7. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology: clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis—2016. *Endo Pract* 2016;22;(suppl 4):S1-S42.
8. World Health Organization. WHO Scientific Group on the assessment of osteoporosis at primary health care level: Summary meeting report; May5-7, 2004, Brussels, Belgium. Geneva, Switzerland: World Health Organization, 2007;1-17.
9. Dolores Shoback, Clifford J Rosen, Dennis M Black, Angela M Cheung, M Hassan Murad, Richard Eastell, Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update, *The Journal of Clinical Endocrinology & Metabolism*, Volume 105, Issue 3, March 2020, Pages 587–594, <https://doi.org/10.1210/clinem/dgaa048>
10. Evenity [package insert]. Amgen. Thousand Oaks, CA 91320. April 2019
11. Saag KG, Peteren J, Brandi ML, et al. Romosozumab or alendronate for fracture prevention in women with osteoporosis. *N Engl J Med* 2017; 377: 1417-1427.
12. Cosman F, Crittenden DB, Ferrari S, et al. FRAME study: the foundation effect of building bone with 1 year of romosozumab leads to continued lower fracture risk after transition to denosumab. *J Bone Miner Res* 2018;33:1219-1226.
13. Camacho, P., Petak, S., Binkley, N., Diab, D., Eldeiry, L., Farooki, A., Harris, S., Hurley, D., Kelly, J., Lewiecki, E., Pessah-Pollack, R., McClung, M., Wimalawansa, S. and Watts, N., 2020. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS/AMERICAN COLLEGE OF ENDOCRINOLOGY CLINICAL PRACTICE GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS—2020 UPDATE. *Endocrine Practice*, 26(Supplement 1), pp.1-46.
14. https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/761062Orig1s000ltr.pdf
15. Liu CL, Lee HC, Chen CC, Cho DY. Head-to-head comparisons of bisphosphonates and teriparatide in osteoporosis: a meta-analysis. *Clin Invest Med*. 2017 Jun 26;40(3):E146-E157. doi: 10.25011/cim.v40i3.28394. PMID: 28653616.
16. Benjamin Z Leder, Bruce Mitlak, Ming-yi Hu, Gary Hattersley, Richard S Bockman, Effect of Abaloparatide vs Alendronate on Fracture Risk Reduction in Postmenopausal Women With Osteoporosis, *The Journal of Clinical Endocrinology & Metabolism*, Volume 105, Issue 3, March 2020, Pages 938–943, <https://doi.org/10.1210/clinem/dgz162>
17. Forteo (teriparatide) [package insert]. Eli Lilly and Company. Indianapolis, IN 46285. November 2020.
18. Calcitonin-salmon (Miacalcin) [package insert]. Myan Institutional LLC. Rockford, IL 61103. September 2017.
19. Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society. *Menopause*. 2021 Sep 1;28(9):973-997. doi: 10.1097/GME.0000000000001831. PMID: 34448749.
20. Vertebral fractures. IOF International Osteoporosis Foundation. Accessed November 27, 2024. <https://www.osteoporosis.foundation/health-professionals/fragility-fractures/assessing-vertebral-fractures#:~:text=Grades%20are%20assigned%20to%20each,40%25%20loss%20of%20vertebral%20height>

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
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Osteoporosis 2025-12.docx	12/2025	Matthew Garrett, PharmD

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