Bone Metabolism Agents

Goal(s):

- To ensure appropriate drug use and safety of bone metabolism agents by authorizing utilization in specified patient populations.

Length of Authorization:

- 12 to 24 months

Requires PA:

- Non-preferred drugs

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this an OHP-funded condition?	**Yes:** Go to #3	**No:** Current age ≥ 21 years: Pass to RPh. Deny; not funded by the OHP Current age < 21 years: Go to #3
3. Will the prescriber consider a change to a preferred product? Note: • Preferred products do not require a PA. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee	**Yes:** Inform prescriber of covered alternatives in class	**No:** Go to #4
4. Has the patient tried and failed an oral bisphosphonate (alendronate, risedronate, or ibandronate) or do they have contraindications to these treatments? (document contraindication, if any)	**Yes:** Go to #5	**No:** Pass to RPh; deny and recommend trial of oral bisphosphonate
5. Is the request for denosumab?	**Yes:** Go to #6	**No:** Go to #7

Approval Criteria		
6. Is denosumab being prescribed for one of the following reasons: • Treatment of postmenopausal women with osteoporosis at high risk for fracture • Treatment to increase bone mass in men with osteoporosis at high risk for fracture • Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture • Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer • Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	**Yes:** Go to #8	**No:** Pass to RPh; Deny; medical appropriateness
7. Is the request for raloxifene?	**Yes:** Go to #8	**No:** Go to #9
8. Is the patient pregnant, or for raloxifene requests, at increased risk for thromboembolism or stroke?	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: inform prescriber of pregnancy category X and for raloxifene: boxed warning for venous thromboembolism and stroke.	**No:** Approve for up to 12 months
9. Is the request for teriparatide and is the patient at high risk for fracture? Examples include: • Postmenopausal women with osteoporosis and T-score ≤ - 2.5 or history of fracture • Men with primary or hypogonadal osteoporosis* • Men or women with osteoporosis associated with sustained systemic glucocorticoid therapy	**Yes:** Go to #12	**No:** Go to #10

Approval Criteria		
10. Is the request for abaloparatide and is the patient a postmenopausal woman aged 49 to 86 years with osteoporosis at high risk for fracture? Inclusion criteria from the ACTIVE[1] trial: • Women with T score between - 2.5 and -5.0 AND radiologic evidence of vertebral fracture or history of nonvertebral fracture within the past 5 years OR • Women aged 65 years or older with T score between -3.0 and -5.0 without history of fracture OR T score between -2.0 and 5.0 with history of fracture.	**Yes:** Go to #11	**No:** Go to #13
11. Has the patient received treatment with anticonvulsants that affect Vitamin D metabolism (phenobarbital, phenytoin, carbamazepine or primidone) or with chronic heparin within the past 6 months OR has the patient received daily treatment with oral, intranasal, or inhaled corticosteroids in the past 12 months?	**Yes:** Pass to RPh. Deny; medical appropriateness. (These patients were excluded from the ACTIVE[1] trial)	**No:** Go to #12.
12. Does the patient meet one of the following conditions: a. Concomitant bisphosphonate; or b. Pediatric or young adult with open epiphyses; or c. History of osteosarcoma or skeletal malignancies; or d. Metabolic bone disease; or e. Underlying hypercalcemic disorders; or f. Unexplained elevated alkaline phosphatase levels?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Approve for up to 24 months (depending on when therapy was initiated. Teriparatide and abaloparatide are only FDA approved for a total duration of therapy of 2 years.)
13. Is the request for romosozumab and is the patient a postmenopausal women with osteoporosis and T-score ≤ - 2.5 or history of fracture?	**Yes:** Go to #14	**No:** Go to #15

Approval Criteria		
14. Has the patient had a myocardial infarction or stroke within the past year?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Approve for up to 12 months maximum.* *Note: FDA has only approved use of romosozumab for a total of 12 months. If continued osteoporosis therapy is warranted, continue therapy with an anti-resorptive agent (e.g. bisphosphonates, denosumab, or raloxifene).
15. RPh only: All other indications need to be evaluated as to whether they are funded by the OHP or not.	If funded and clinic provides supporting literature, approve for up to 12 months	If non-funded and current age ≥ 21 years: Pass to RPh. Deny; not funded by the OHP If non-funded and current age < 21 years: Go to #16
16. Is there documentation of medical appropriateness and medical necessity? Definitions for medical appropriateness include use for an FDA indication AND use, contraindication, or intolerance to preferred agents in the class. Medical necessity includes documentation that the diagnosis impacts the patient's health.	**Yes:** Approve for up to 12 months	**No:** Pass to RPh; deny medical appropriateness or medical necessity

** FDA approved osteoporosis treatments for men include alendronate, risedronate, zoledronic acid, teriparatide, and denosumab.*

1. Miller PD, Hattersley G, Riis BJ, et al. Effect of Abaloparatide vs Placebo on New Vertebral Fractures in Postmenopausal Women With Osteoporosis: A Randomized Clinical Trial. JAMA. 2016; 316 (7):722-733. DOI: 10.1001/jama.2016.11136.

P&T Review: *7/19 (DM); 3/18; 7/16; 9/10*
Implementation: *11/1/19; 4/16/18; 8/16, 1/1/11*