

ALASKA MEDICAID
Prior Authorization Criteria

Reclast®, Zometa®
(zoledronic acid)

FDA INDICATIONS AND USAGE^{1,2}

Zoledronic acid is a bisphosphonate, which is an inhibitor of osteoclastic bone resorption. Zoledronic acid binds to the bone matrix, which decreases osteoclastic activity, prevents bone resorption and skeletal calcium release induced by various stimulatory factors released by tumors. Brand names include Reclast® and Zometa®.

APPROVAL CRITERIA^{1,2,3,4,5,6,7}

Reclast®

1. Patient is 18 years of age or older **AND**;
2. Request is for Reclast® for **one of the following indications** (a,b,c,d,or e):
 - a. Treatment of osteoporosis in postmenopausal woman and one of the following (i or ii):
 - i. Prior to therapy, T-score \leq -2.5 (DXA) at the femoral neck or spine or osteoporotic vertebral fracture confirmed by radiographic imaging; **OR**;
 - ii. High risk of fracture, defined as a recent low-trauma hip fracture
 - b. Prevention of osteoporosis in postmenopausal woman with T-score $<$ -1.0 (DXA) at the femoral neck, spine, or total hip, and one of the following (i or ii):
 - i. A 10-year probability of hip fracture \geq 3% per the WHO Fracture Risk Assessment Tool (FRAX) **OR**;
 - ii. A 10-year probability of a major osteoporosis-related fracture \geq 20% per the FRAX;
 - c. Treatment of male with osteoporosis (if hypogonadal osteoporosis, is receiving testosterone but remains at high risk for fracture or has a contraindication to testosterone);
 - d. Treatment or prevention of glucocorticoid-induced osteoporosis when either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to \geq 7.5 mg of prednisone and is expected to remain on glucocorticoids for at least 12 months;
 - e. Treatment of Paget's disease of the bone and one of the following (i, ii, or iii):
 - i. Member is symptomatic **OR**;
 - ii. At risk for complications from the disease **OR**;
 - iii. Serum alkaline phosphatase is elevated \geq 2 times the upper limit of the age specific normal reference range.
3. Patient has a contraindication or has had an inadequate response to oral bisphosphonate therapy **AND**;
4. Patient is not currently receiving therapy with Zometa.

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Zometa®

1. Patient is 18 years of age or older **AND**;
2. Request is for Zometa® for **one of the following indications** (a,b,or c):
 - a. Hypercalcemia of malignancy defined as an albumin-corrected calcium of ≥ 12 mg/dL **OR**;
 - b. Multiple myeloma when used in conjunction with antineoplastic therapy and calcium plus vitamin D supplementation **OR**;
 - c. Bone metastases from solid tumors when used in conjunction with antineoplastic therapy and calcium plus vitamin D supplementation **AND**;
3. Patient is not currently receiving therapy with Reclast®.

DENIAL CRITERIA^{1,2}

1. Failure to meet approval criteria **OR**;
2. Patient has pre-existing hypocalcemia that has not been corrected with adequate supplementation with calcium and vitamin D.

CAUTIONS^{1,2}

- See package inserts:
 - Reclast®
<https://www.novartis.us/sites/www.novartis.us/files/reclast.pdf?campaign=uehcdjebk>
 - Zometa®
https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/203231s011lbl.pdf

DURATION OF APPROVAL

- Initial Approval: 12 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- Reclast® - 1 infusion not exceeding 5mg
- Zometa® - 1 infusion not exceeding 4mg
- HCPCS – J3489

REFERENCES / FOOTNOTES:

1. Reclast [package insert]. East Hanover, NJ; Novartis Pharmaceuticals; April 2020. Accessed December 2021.
2. Zometa [package insert]. Stein, Switzerland; Novartis Pharmaceuticals; March 2016. Accessed December 2021.

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3. Rosen HN, Drezner MK. Overview of the management of osteoporosis in postmenopausal women. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed December 2021.
4. Rosen HN, Saag KG. Prevention and treatment of glucocorticoid-induced osteoporosis. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed December 2021.
5. Singer FR, Bone HG, Hosking DJ, et al. Paget's disease of the bone: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014; 99(12): 4480-4422.
6. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2012; 97(6): 1802-1822.
7. Gralow JR, Bierman JS, Farooki A, et al. NCCN task force report: bone health in cancer care. J Natl Compr Canc Netw. 2013; 11(Suppl 3): S1-S57.