Medical Drug Clinical Criteria

Subject:	Zoledronic Acid (Reclast)		
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Overview

This document addresses the use of zoledronic acid (Reclast) which is a bisphosphonate agent specifically used to inhibit bone resorption. Zoledronic acid is approved for the treatment of osteoporosis, glucocorticoid-induced osteoporosis, Paget's disease, multiple myeloma, bone metastases, hypercalcemia of malignancy, and other indications as applicable.

The American College of Endocrinology (AACE/ACE) (2020) osteoporosis treatment guidelines stratify initial treatment based on risk status. For those at high risk/no prior fractures, initial therapy options include bisphosphonates (alendronate, risedronate, or zoledronic acid) or denosumab. For those at very high risk/prior fractures, initial therapy options are denosumab, abaloparatide, teriparatide, romosozumab, or zoledronic acid. The Endocrine Society osteoporosis guideline update (2020) recommends initial therapy with bisphosphonates (alendronate, risedronate, zoledronic acid, or ibandronate) or alternatively denosumab for those at high risk.

Osteoporosis may be diagnosed by bone mineral density (BMD) testing indicating a T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population. It also may be clinically diagnosed based on a history of a fragility fracture (low trauma fracture).

Higher risk for fracture may be defined as:

1. History of osteoporotic fracture; or
2. Multiple risk factors for fractures, including but not limited to: Prior low-trauma fracture as an adult, advanced age, gender, ethnicity, low bone mineral density (T-score -1.0 to-2.5), low body weight (<57.6kg), family history of osteoporosis, use of glucocorticoids (daily dosage equivalent to 5 mg or greater prednisone for at least 3 months), current cigarette smoking, excessive alcohol consumption (3 or more drinks per day), secondary osteoporosis (such as rheumatoid arthritis), early menopause, height loss of kyphosis, fall risk and low calcium intake; or
3. Failure or intolerance to other osteoporosis therapies.

A failure of other osteoporosis therapies, otherwise known as refractory disease, may be defined as a decline in BMD while on therapy (≥5%) or a fragility fracture while on therapy.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Reclast (zoledronic acid)

Requests for Reclast (zoledronic acid) may be approved for any of the following conditions:

I. Glucocorticoid-induced osteoporosis in men and women who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and who are expected to remain on glucocorticoids for at least 12 months; **OR**
II. Osteoporosis, treatment to increase bone mass in men; **OR**
III. Osteoporosis, treatment and prevention – in postmenopausal women; **OR**
IV. Paget's disease of bone in men and women – treatment indicated with elevations in serum alkaline phosphatase of two times or higher than the upper limit of the age-specific normal reference range, or those who are symptomatic, or those at risk for complications from their disease.

Zoledronic acid 4 mg

Requests for Zoledronic acid 4 mg may be approved for any of the following conditions:

I. Bone metastases on imaging or bone pain associated with metastases from breast, prostate, lung, mastocytosis, kidney, thyroid, or other solid tumors; **OR**
II. Hypercalcemia of malignancy, treatment; **OR**
III. Multiple myeloma; **OR**
IV. Breast cancer, prevention of bone loss secondary to adjuvant hormone therapy (such as aromatase inhibitors) (NCCN 2A); **OR**
V. Prevention of osteoporosis during androgen deprivation therapy in prostate cancer (NCCN 2A); **OR**
VI. Bone disease associated with Langerhans Cell Histiocytosis (NCCN 2A).

Requests for zoledronic acid agents (Reclast, Zolendronic acid 4 mg) may not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Bisphosphonate Agent Quantity Limit

Drug	Limit
Reclast (zoledronic acid) 5 mg/100 mL	100 mL (5 mg) once per year

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3489	Injection, zoledronic acid, 1 mg [Reclast, zoledronic acid 4mg]

ICD-10 Diagnosis

C00.0-C80.2	Malignant neoplasms
C81.00-C81.99	Hodgkin lymphoma
C82.00-C86.6	Non-Hodgkin lymphoma
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]
C90.00-C90.32	Multiple myeloma and malignant plasma cell neoplasms
C96.0	Multifocal and multisystemic (disseminated) Langerhans-cell histiocytosis
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis
C96.6	Unifocal Langerhans-cell histiocytosis
D00.00-D09.9	In situ neoplasms
D47.01-C47.09	Mast cell neoplasms of uncertain behavior
E83.52	Hypercalcemia
M80.00XA-M80.88XS	Osteoporosis with current pathological fracture
M81.0-M81.8	Osteoporosis without current pathological fracture
M85.80-M85.9	Other specified disorders of bone density and structure [osteopenia]
M88.0-M88.9	Osteitis deformans [Paget's disease of bone]
Z79.52	Long term (current) use of systemic steroids
Z79.811	Long term (current) use of aromatase inhibitors
Z79.83	Long term (current) use of bisphosphonates

Z85.00-Z85.9	Personal history of malignant neoplasm
Z92.241	Personal history of systemic steroid therapy

Document History

Revised: 08/16/2024
Document History:

- 08/16/2024 – Annual Review: add metastases from mastocytosis, formatting. Coding Reviewed: Added ICD-10-CM D47.01-D47.09.
- 08/18/2023 – Annual Review: update document name. Coding Reviewed: No changes.
- 08/19/2022 – Annual Review: Add Langerhans bone disease. Coding reviewed: Added ICD-10-CM C96.0, C96.5, C96.6.
- 08/20/2021- Annual Review: No changes. Coding reviewed: No changes.
- 02/19/2021 – Annual Review: Remove obsolete brand Zometa. Coding Reviewed: Removed the word Zometa from J3489 description and added generic zoledronic acid 4mg to description..
- 12/21/2020 – Add quantity limits for Reclast.
- 08/21/2020 – Annual Review: No changes. Coding reviewed: No changes.
- 08/16/2019 – Annual Review: Wording and formatting updates. Coding Reviewed: No changes.
- 08/17/2018 – Annual Review: Initial review of zoledronic acid agents criteria. Update Zometa PA to delete indication for prevention of bone loss in premenopausal females with early stage breast cancer as it does not meet off-label policy requirements.
- 11/09/2018 – Code review: No changes made. Changes to criteria to delete indication for premenopausal breast cancer, but existing codes do not specify premenopausal vs. post-menopausal and are still relevant.

References

1. 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 – 2020 Update. *Endocrine Practice*. 2020;26(1):1-46.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2024. Updated periodically.
6. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 5, May 2019, Pages 1595–1622, https://doi.org/10.1210/jc.2019-00221.
7. Shoback D, Rosen CJ, Black DM, et al. 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.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
9. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 20, 2024.
    a. Histiocytic Neoplasms. V1.2024. Revised March 15, 2024.
    b. Systemic Mastocytosis. V3.2024. Revised April 24, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.