Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Zoledronic acid (Reclast®)	MP-RX-FP-152-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of Zoledronic acid (Reclast®), a bisphosphonate agent approved by the Food and Drug Administration (FDA) for the treatment and prevention of postmenopausal osteoporosis, treatment to increase bone mass in men with osteoporosis, treatment and prevention of glucocorticoid-induced osteoporosis and treatment of Paget's disease of bone in men and women.

Background Information

Zoledronic acid is a bisphosphonate and acts primarily on bone. It is an inhibitor of osteoclast-mediated bone resorption.

Reclast is administered as an intravenous infusion every one to two years.

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:

- History of osteoporotic fracture; or
- 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
- Failure or intolerance to other osteoporosis therapies.

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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.

The safety and effectiveness of Reclast for the treatment of osteoporosis is based on clinical data of three years duration. The optimal duration of use has not been determined. All patients on bisphosphonate therapy should have the need for continued therapy reevaluated on a periodic basis. Patients at low-risk for fracture should be considered for drug discontinuation after 3 to 5 years of use. Patients who discontinue therapy should have their risk for fracture reevaluated periodically.

Approved Indications

Reclast is approved by the FDA for the treatment and prevention of postmenopausal osteoporosis, treatment to increase bone mass in men with osteoporosis, treatment and prevention of glucocorticoid-induced osteoporosis and treatment of Paget's disease of bone in men and women.

Other Uses

None

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J3489	Injection, zoledronic acid, 1 mg

ICD-10	Description
M80.00XA-M80.88XS	Osteoporosis with current pathological fracture
M81.0-M81.8	Osteoporosis without current pathological fracture
Z79.52	Long term (current) use of systemic steroids
M88.0	Osteitis deformans [Paget's disease of bone]
Z92.241	Personal history of systemic steroid therapy

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Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Zoledronic acid (Reclast®)

A. Criteria For Initial Approval

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.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Zoledronic acid (Reclast®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) if the following information is provided:
   A. After a single treatment for Paget's disease, long periods of remission are usually observed, and there is not data available for retreatment. However, as per manufacturer's information, MMM will consider retreatment medically necessary in patients with documented evidence of relapse based on increases in serum alkaline phosphatase levels, failure to achieve normalization of alkaline phosphatase levels or in those patients with symptoms. Documentation of treatment failure must be provided; **AND**
   B. Documentation of Serum Creatinine and Creatinine Clearance calculated based on actual body weight using Cockcroft-Gault formula; **AND**
   C. Documentation of serum calcium levels or documentation that patient is taking calcium and Vitamin D supplementation.

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C. Authorization Duration

i. Initial Approval Duration: Up to 12 months

A. For prevention of postmenopausal osteoporosis: Reclast may be repeated every 24 months.

ii. Reauthorization Approval Duration: Up to 12 months

D. **Conditions Not Covered**

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Requests for zoledronic acid may not be approved when the above criteria are not met and for all other indications.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

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Indication	Recommended Dosing Schedule
• Treatment of postmenopausal osteoporosis • Treatment to increase bone mass in men with osteoporosis • Treatment and prevention of glucocorticoid-induced osteoporosis	5mg IV once a year
• Prevention of postmenopausal osteoporosis	5mg IV once every 2 years
• Treatment of Paget's disease of bone	Single 5mg infusion
Exceptions	
Contraindications: • Hypocalcemia • Patients with creatinine clearance less than 35 mL/min and in those with evidence of acute renal impairment	

Reference Information

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.: 2023. 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; 2023. 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.; 2023; Updated periodically.

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.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 03/31/2025	Validation of information to ensure is up to date. Word formatting, indentation alignment.	4/16/2025	5/6/2025
Policy Inception	New Medical Policy creation	3/25/2024	6/28/2024