Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Zoledronic acid (Reclast)	MP-RX-FP-152-24	☒ MMM MA ☒ MMM MultiHealth	6/28/2024	03/24/2026
			Last Review Date:	Frequently Revision:
			03/24/2026	Annual

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

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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.

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

A. Treatment and prevention of postmenopausal osteoporosis.
B. Treatment to increase bone mass in men with osteoporosis.
C. Treatment and prevention of glucocorticoid-induced osteoporosis.
D. Treatment of Paget's disease of bone in men and women.

Other Uses

A. 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- M80.8B9S	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
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**

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B. Documentation of Serum Creatinine and Creatinine Clearance calculated based on actual body weight using Cockcroft-Gault formula; **AND**

C. Documentation calcium levels or documentation that patient is taking calcium and Vitamin D supplementation; **AND**

D. Documentation that, per Reclast prescribing information, a routine oral exam has been performed, and the patient has been evaluated for thigh or groin pain (to rule out atypical femur fracture) and for severe bone, joint, or muscle pain.

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.
   - For patients at low risk for fracture, discontinue after 3 – 5 years of use.

D. Conditions Not Covered

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

i. Requests for Reclast may not be approved for any of the following conditions:

A. Hypocalcemia;

OR

B. Patients with creatinine clearance less than 35 mL/min;

OR

C. Patients with evidence of acute renal impairment;

OR

D. Patients receiving zoledronic acid 4 mg;

OR

E. When the above criteria are not met and for all other indications.

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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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Drug: Reclast® (zoledronic acid inj) 5mg/100 ml ready to infuse solution	
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. • Patients should receive 1500 mg elemental calcium and 800 international units vitamin D daily.
Exceptions	
• Prior to each dose, obtain SCr and calculate the CrCl using the Cockcroft-Gault formula with actual body weight. o Use with caution in patients with CrCl <80 mL/minute. o CrCl <35 mL/minute or evidence of acute kidney impairment: IV: Use contraindicated due to increased risk of nephrotoxicity and lack of efficacy and safety data. o Use in patients with adynamic bone disease may further suppress bone formation and theoretically increase the risk of fracture and vascular calcification.	

Reference Information

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4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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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.
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9. Novartis Pharmaceuticals Corporation. (2024). *Reclast (zoledronic acid) injection [Prescribing information]*. Retrieved January 26, 2026, from https://www.novartis.com/us-en/sites/novartis_us/files/reclast.pdf
10. UpToDate. (2024). *Zoledronic acid: Drug information*. Retrieved January 26, 2026, from https://www.uptodate.com/contents/zoledronic-acid-drug-information?search=reclast&source=panel_search_result&selectedTitle=1~72&usage_type=panel&kp_tab=drug_general&display_rank=1

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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Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Focus review	A typographical error was corrected in the "Conditions Not Covered" section.	N/A	N/A
Annual Review	Coding Reviewed: added ICD10 codes: M80.8B9S, M85.8-M85.9, M88.9. Added safety documentation requirement to Criteria for Continuation of Therapy and discontinuation after 3-5 years for patients at low risk for fracture. Added Conditions Not Covered per FDA label contraindications. Clarified Vit D and calcium supplementation for Paget's disease and serum creatinine dosing exceptions. Added available dosage form to the Qty limits table. Updated references.	3/17/2026	3/24/2026
Annual Review	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