Clinical Policy: Zoledronic Acid (Reclast)

Reference Number: CP.PHAR.59
Effective Date: 03.11
Last Review Date: 02.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Zoledronic acid (Reclast®) is a bisphosphonate.

FDA Approved Indication(s)

Reclast is indicated:

- For the treatment of osteoporosis in postmenopausal women (PMO). In postmenopausal women with osteoporosis, diagnosed by bone mineral density (BMD) or prevalent vertebral fracture, Reclast reduces the incidence of fractures (hip, vertebral, and non-vertebral osteoporosis-related fractures). In patients at high risk of fracture, defined as a recent low-trauma hip fracture, Reclast reduces the incidence of new clinical fractures;
- For the prevention of osteoporosis in postmenopausal women (PMO);
- For the treatment to increase bone mass in men with osteoporosis;
- For the treatment and prevention of glucocorticoid-induced osteoporosis (GIO 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;
- For the treatment of Paget's disease of bone in men and women with elevations in serum alkaline phosphatase (ALP) 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.

Limitation(s) of use: 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 re-evaluated 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 re-evaluated periodically.

Zoledronic acid (formerly Zometa®) is indicated:

- For the treatment of hypercalcemia of malignancy defined as an albumin-corrected calcium (cCa) of greater than or equal to 12 mg/dL (3.0 mmol/L);
- For the treatment of patients with multiple myeloma (MM);
- For the treatment of patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy.

Limitation(s) of use: The safety and efficacy of zoledronic acid in the treatment of hypercalcemia associated with hyperparathyroidism or with other non-tumor-related conditions have not been established.

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

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It is the policy of health plans affiliated with Centene Corporation® that zoledronic acid is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Osteoporosis (must meet all):
1. Prescribed for one of the following uses (a or b):
   a. Treatment or prevention of PMO or GIO;
   b. Treatment of male osteoporosis;
2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
3. Failure of a 12-month trial of an oral bisphosphonate *(see Appendix B; generic alendronate* is preferred)* at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for oral bisphosphonates*
4. If request is for brand Reclast, member must use zoledronic acid 5 mg/100 mL (generic Reclast), unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 5 mg.

Approval duration:
Medicaid/HIM –
- Osteoporosis treatment: 12 months (one infusion)
- Osteoporosis prevention: 24 months (one infusion)

Commercial – 6 months or to the member's renewal date, whichever is longer

B. Paget Disease (must meet all):
1. Diagnosis of Paget disease of the bone;
2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
3. If request is for brand Reclast, member must use zoledronic acid 5 mg/100 mL (generic Reclast), unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 5 mg.

Approval duration:
Medicaid/HIM – 12 months (one infusion)
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Hypercalcemia of Malignancy (must meet all)**:**
1. Request is for zoledronic acid 4 mg/5 mL or 4 mg/100 mL (formerly Zometa);
2. Diagnosis of hypercalcemia of malignancy:
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
5. Albumin-corrected calcium ≥ 12 mg/dL;
5. Dose does not exceed 4 mg.

Approval duration:
Medicaid/HIM – 1 week (one infusion)
Commercial – 6 months or to the member's renewal date, whichever is longer

D. Multiple Myeloma or Solid Tumor (must meet all)**:**
1. Request is for zoledronic acid 4 mg/5 mL or 4 mg/100 mL (formerly Zometa);
2. Diagnosis of one of the following (a or b):
   a. MM, and member is receiving or initiating therapy (e.g., chemotherapy, transplant) for symptomatic disease;
   b. Bony metastasis from solid tumor (e.g., breast, kidney, lung, prostate, thyroid);
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
5. Dose does not exceed 4 mg.

Approval duration:
Medicaid/HIM – 3 months (one infusion every 3 weeks)
Commercial – 6 months or to the member's renewal date, whichever is longer

E. Prostate/Breast Cancer - Fracture Prevention (off-label) (must meet all)**:**
1. Diagnosis of one of the following (a or b):
   a. Prostate cancer, and member is receiving androgen deprivation therapy (e.g., leuprolide (Lupron®), bicalutamide (Casodex®), nilutamide (Nilandron®));

b. Breast cancer, and member is receiving adjuvant endocrine therapy (e.g., tamoxifen or aromatase inhibitors such as anastrozole (Arimidex®), exemestane (Aromasin®) or letrozole (Femara®));
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
4. If request is for brand Reclast, member must use zoledronic acid 5 mg/100 mL (generic Reclast), unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 4 mg;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:
Medicaid/HIM – 12 months (one infusion for prostate cancer, two infusions for breast cancer)
Commercial – 6 months or to the member's renewal date, whichever is longer

F. Systemic Mastocytosis (off-label) (must meet all)**:**
1. Request is for zoledronic acid 4 mg/5 mL or 4 mg/100 mL (formerly Zometa);
2. Diagnosis of systemic mastocytosis;
3. Member has osteopenia or osteoporosis with bone pain;
4. Prescribed by or in consultation with an oncologist;
5. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 4 mg;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:
Medicaid/HIM – 3 months (one infusion every 3 weeks)
Commercial – 6 months or to the member's renewal date, whichever is longer

G. Histiocytic Neoplasms – Langerhans Cell Histiocytosis (off-label) (must meet all)**:**
1. Request is for zoledronic acid 4 mg/5 mL or 4 mg/100 mL (formerly Zometa);
2. Diagnosis of Langerhans cell histiocytosis;
3. Member has multifocal bone disease or unifocal Langerhans cell histiocytosis with isolated bone disease;
4. Prescribed by or in consultation with an oncologist;
5. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 4 mg;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:
Medicaid/HIM – 3 months (one infusion every 4 weeks)

Commercial – 6 months or to the member's renewal date, whichever is longer

H. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Osteoporosis and Paget Disease of Bone (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 5 mg.

Approval duration:

Medicaid/HIM –

- Osteoporosis treatment and Paget disease: 12 months (one infusion)
- Osteoporosis prevention: 24 months (one infusion)

Commercial – 6 months or to the member's renewal date, whichever is longer

B. Oncology-Related Indications (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving zoledronic acid for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 4 mg;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:
Medicaid/HIM –
- Hypercalcemia of malignancy: 1 week (one infusion)
- Prostate cancer and breast cancer: 12 months (one infusion for prostate cancer, two infusions for breast cancer)
- All other indications: 12 months (one infusion every 3 weeks)

Commercial – 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALP: alkaline phosphatase
BMD: bone mineral density
cCa: corrected calcium
FDA: Food and Drug Administration
GIO: glucocorticoid-induced osteoporosis
MM: multiple myeloma
PMO: postmenopausal osteoporosis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Oral bisphosphonates		
alendronate (Fosamax®)	Treatment/prevention: PMO Treatment: GIO, male osteoporosis *See prescribing information for dose.*	Varies
Fosamax® Plus D (alendronate / cholecalciferol)	Treatment: PMO, male osteoporosis *See prescribing information for dose.*	
risedronate (Actonel®, Atelvia®)	Actonel: Treatment/prevention: PMO, GIO Treatment: male osteoporosis Atelvia: Treatment: PMO *See prescribing information for dose.*	
ibandronate (Boniva®)	Treatment/prevention: PMO *See prescribing information for dose.*	

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity to any product component
  - Reclast: hypocalcemia, creatinine clearance < 35 mL/min, acute renal impairment
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Zoledronic acid (Reclast)	Treatment: PMO, male osteoporosis Treatment/prevention: GIO	5 mg IV once a year	5 mg/year
	Prevention: PMO	5 mg IV once every 2 years	5 mg/2 years
	Paget disease	5 mg IV once; retreatment may be considered	5 mg
Zoledronic acid (formerly Zometa)	Hypercalcemia of malignancy	4 mg as a single-use IV infusion; may re-treat with 4 mg after a minimum of 7 days	4 mg/infusion
	MM Solid tumor - bone metastasis	4 mg as a single-use IV infusion every 3 to 4 weeks	4 mg/3 weeks

VI. Product Availability

Drug Name	Availability
Zoledronic acid (Reclast)	Ready-to-infuse solution: 5 mg/100 mL

Drug Name	Availability
Zoledronic acid (formerly Zometa)	Ready-to-infuse solution: 4 mg/100 mL Single-use vial concentrate: 4 mg/5 mL

VII. References

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Paget Disease
14. Singer FR, Bone HG 3rd, 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.
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23. National Comprehensive Cancer Network. Thyroid Carcinoma Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed November 5, 2024.
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Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3489	Injection, zoledronic acid, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: The MM/solid tumor common criteria line item, at risk for skeletal related event, is removed for solid tumor and for MM is replaced with receiving or initiating therapy for symptomatic disease per pivotal trials/NCCN; revised approval duration and frequency of treatment for prostate/breast cancer fracture prevention from once every 3 weeks for 3 months to once every year for prostate cancer and twice a year for breast cancer; references reviewed and update.	11.03.20	02.21
1Q 2022 annual review: Zometa - added criteria for off label indication of histiocytic neoplasms per NCCN guidelines; references reviewed and updated.	11.05.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.12.22	
1Q 2023 annual review: as a result of Zometa branded product being obsolete, removed distinction between Zometa and Reclast, removed requirements that ensured both products are not used in combination; references reviewed and updated.	11.02.22	02.23
1Q 2024 annual review: for osteoporosis, clarified failure of "generic" alendronate is preferred; for Paget's disease, removed initial criteria requiring failure of an oral bisphosphonate per guidelines; removed Paget's disease indication for oral bisphosphonates from Appendix B; references reviewed and updated.	10.20.23	02.24
1Q 2025 annual review: for brand Reclast requests added redirection to generic; for initial requests for oncology indications other than prostate and breast cancer, added clarification that request is for zoledronic acid 4 mg/5 mL or 4 mg/100 mL (formerly Zometa); references reviewed and updated.	10.22.24	02.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.