CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Bone Modifiers – Zoledronic Acid (Reclast) Utilization Management Medical Policy
- Reclast® (zoledronic acid intravenous infusion – Novartis, generic)

REVIEW DATE: 03/18/2026

OVERVIEW

Zoledronic acid intravenous infusion (Reclast), a bisphosphonate, is indicated for the following uses:[1]
- **Glucocorticoid-induced osteoporosis**, for treatment and prevention in men and women who are either initiating or continuing systemic glucocorticoids (e.g., prednisone 7.5 mg or greater) and who are anticipated to remain on glucocorticoids for at least 12 months.
- **Osteoporosis, prevention in postmenopausal women**.
- **Osteoporosis, treatment in men** to increase bone mass.
- **Osteoporosis, treatment in postmenopausal women**.
- **Paget's disease of bone**, treatment in men and women.

Limitations of Use: The safety and effectiveness of Reclast for the treatment of osteoporosis is based on clinical data of three years duration.[1] 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.

Of note, zoledronic acid intravenous infusion is also available under the brand name (Zometa®) but is not included in this policy.[2]

Zoledronic acid injection (Zometa) is indicated for the treatment of hypercalcemia of malignancy, multiple myeloma, and bone metastases from solid tumors.[2] Although not indicated, zoledronic acid injection (Reclast) has been used in patients, mainly children, with osteogenesis imperfecta and benefits were noted, such as increases in bone mineral density.[1,3-9] Zoledronic acid 5 mg IV once yearly is recommended for treatment-related bone loss in patients with prostate cancer receiving androgen deprivation therapy by the National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer (version 5.2026 – January 23, 2026).[10]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of zoledronate acid injection (Reclast). Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Regarding the approval duration of one dose, the approval is for 30 days, which is an adequate duration for the patient to receive one dose. In the approval indication for zoledronic acid injection (Reclast), as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of zoledronate acid injection (Reclast) is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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1. **Glucocorticoid-Induced Osteoporosis – Prevention and Treatment.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is either initiating or continuing systemic glucocorticoids; AND
     Note: An example of a systemic glucocorticoid is prednisone.
   - **B)** Patient meets ONE of the following (i, ii, iii, or iv):
     - **i.** Patient has tried zoledronic acid intravenous infusion (Reclast); OR
     - **ii.** Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets ONE of the following (a or b):
       Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), and Boniva (ibandronate tablets).
       - **a)** According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
         Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
       - **b)** Patient has experienced significant intolerance to an oral bisphosphonate; OR
         Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, and femoral fracture.
     - **iii.** Patient cannot take an oral bisphosphonate due to ONE of the following (a, b, or c):
       - **a)** Patient cannot swallow or has difficulty swallowing; OR
       - **b)** Patient cannot remain in an upright position post-oral bisphosphonate administration; OR
       - **c)** Patient has a pre-existing gastrointestinal medical condition in which intravenous bisphosphonate therapy may be warranted; OR
         Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, and abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).
     - **iv.** Patient has had an osteoporotic fracture or a fragility fracture.

   Dosing. Approve one 5 mg infusion given intravenously up to once every year.

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2. **Osteoporosis – Prevention for a Postmenopausal Patient.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has had a T-score (current or at any time in the past) between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist); OR
     - **ii.** Patient has had an osteoporotic fracture or a fragility fracture; AND
   - **B)** Patient meets ONE of the following (i, ii, iii, or iv):
     - **i.** Patient has tried zoledronic acid intravenous infusion (Reclast); OR

ii. Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets ONE of the following (a or b):
Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), and Boniva (ibandronate tablets).
a) According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
b) Patient has experienced significant intolerance to an oral bisphosphonate; OR
Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, and femoral fracture.

iii. Patient cannot take an oral bisphosphonate due to ONE of the following (a, b, or c):
a) Patient cannot swallow or has difficulty swallowing; OR
b) Patient cannot remain in an upright position post oral bisphosphonate administration; OR
c) Patient has a pre-existing gastrointestinal medical condition in which intravenous bisphosphonate therapy may be warranted; OR
Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, and abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).

iv. Patient has had an osteoporotic fracture or a fragility fracture; AND

C) If the patient has received the requested medication previously, at least 24 months has elapsed since the last dose.

Dosing. Approve one 5 mg infusion given intravenously up to once every 2 years.

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3. Osteoporosis – Treatment for a Man*. Approve for 1 year if the patient meets BOTH of the following (A and B):

A) The patient meets ONE of the following (i, ii, or iii):
i. Patient has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist); OR
ii. Patient has had an osteoporotic fracture or a fragility fracture; OR
iii. Patient meets BOTH of the following (a and b):
a) Patient has low bone mass; AND
Note: An example of low bone mass includes a T-score (current or at any time in the past) between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist).
b) According to the prescriber, patient is at high risk of fracture; AND

B) Patient meets ONE of the following (i, ii, iii, or iv):
i. Patient has tried zoledronic acid intravenous infusion (Reclast); OR
ii. Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets ONE of the following (a or b):
Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), and Boniva (ibandronate tablets).
a) According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR

Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.

b) The patient has experienced significant intolerance to an oral bisphosphonate; OR
Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, and femoral fracture.

iii. Patient cannot take an oral bisphosphonate due to ONE of the following (a, b, or c):
- **a)** Patient cannot swallow or has difficulty swallowing; OR
- **b)** Patient cannot remain in an upright position post oral bisphosphonate administration; OR
- **c)** Patient has a pre-existing gastrointestinal medical condition in which intravenous bisphosphonate therapy may be warranted; OR
  Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, and abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).

iv. Patient has had an osteoporotic fracture or a fragility fracture.

* Refer to the Policy Statement.

Dosing. Approve one 5 mg infusion given intravenously up to once every year.

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4. Osteoporosis – Treatment for a Postmenopausal Patient. Approve for 1 year if the patient meets BOTH of the following (A and B):

A) Patient meets ONE of the following (i, ii, or iii):
- **i.** Patient has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist); OR
- **ii.** Patient has had an osteoporotic fracture or a fragility fracture; OR
- **iii.** Patient meets BOTH of the following (a and b):
  - **a)** Patient has low bone mass; AND
    Note: An example of low bone mass includes a T-score (current or at any time in the past) between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist).
  - **b)** According to the prescriber, patient is at high risk for fracture; AND

B) Patient meets ONE of the following (i, ii, iii, or iv):
- **i.** Patient has tried ibandronate intravenous infusion (Boniva IV) or zoledronic acid intravenous infusion (Reclast); OR
- **ii.** Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets ONE of the following (a or b):
  Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), and Boniva (ibandronate tablets).
  - **a)** According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
    Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
  - **b)** Patient has experienced significant intolerance to an oral bisphosphonate; OR
    Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, and femoral fracture.

iii. Patient cannot take an oral bisphosphonate due to ONE of the following (a, b, or c):
- **a)** Patient cannot swallow or has difficulty swallowing; OR
- **b)** Patient cannot remain in an upright position post oral bisphosphonate administration; OR
- **c)** Patient has a pre-existing gastrointestinal medical condition in which intravenous bisphosphonate therapy may be warranted; OR
  Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, and abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).

iv. Patient has had an osteoporotic fracture or a fragility fracture.

Dosing. Approve one 5 mg infusion given intravenously up to once every year.

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5. Paget's Disease of Bone. Approve for one dose if the patient meets ONE of the following (A, B, or C):
- **A)** Patient has elevations in serum alkaline phosphatase of two times higher than the upper limit of the age-specific normal reference range; OR
- **B)** Patient is symptomatic; OR
  Note: Examples of symptoms include bone pain, hearing loss, or osteoarthritis.
- **C)** Patient is at risk for complications from their disease.
  Note: Examples of disease complications include immobilization, bone deformity, fractures, and nerve compression syndrome.

Dosing. Approve one 5 mg intravenous infusion.

Other Uses with Supportive Evidence

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6. Osteogenesis Imperfecta. Approve for 1 year.

Dosing. Dosing information is limited. Approve up to 0.05 mg per kg intravenously given no more frequently than once every 3 months.

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7. Treatment of Bone Loss in a Patient with Prostate Cancer Receiving Androgen Deprivation Therapy. Approve for 1 year if the patient is receiving androgen deprivation therapy.
Note: Examples of androgen deprivation therapy are Lupron Depot (leuprolide depot suspension injection), Eligard (leuprolide acetate suspension injectable), Trelstar (triptorelin pamoate suspension injection), Zoladex (goserelin implant), and Orgovyx (relugolix tablets).

Dosing. Approve one 5 mg infusion given intravenously up to once every year.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage of zoledronic acid injection (Reclast) is not recommended in the following situations:

1. Concurrent Use of Zoledronic Acid Intravenous Infusion (Reclast) with Other Medications for Osteoporosis.

Note: Examples of medications for osteoporosis that zoledronic acid intravenous infusion (Reclast) should not be given with include oral bisphosphonates (alendronate, risedronate, ibandronate), other intravenous bisphosphonates (e.g., intravenous ibandronate [Boniva]), Evenity (romosozumab-aqqg subcutaneous injection), Prolia (denosumab subcutaneous injection), Forteo (teriparatide subcutaneous injection, generic), Tymlos (abaloparatide subcutaneous injection), and calcitonin nasal spray. This applies only to osteoporosis-related indications. However, this does NOT exclude use of calcium and/or vitamin D supplements in combination with zoledronic acid intravenous infusion (Reclast). This criterion applies only to osteoporosis-related indications.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Reclast® intravenous infusion [prescribing information]. East Hanover, NJ: Novartis; February 2026.
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3. Biggin A, Munns CF. Long-term bisphosphonate therapy in osteogenesis imperfecta. *Curr Osteoporos Rep*. 2017;15(5):412-418.
4. Barros ER, Saraiva GL, de Oliveira P, Lazaretti-Castro M. Safety and efficacy of a 1-year treatment with zoledronic acid compared with pamidronate in children with osteogenesis imperfecta. *J Pediatr Endocr Met*. 2012;25(5-6):485-491.
5. Panigrahi I, Das RR, Sharda S, et al. Response to zoledronic acid in children with type III osteogenesis imperfecta. *J Bone Miner Metab*. 2010;28:451-455.
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7. Vuorimies I, Toiviainen-Salo S, Hero M, Makitie O. Zoledronic acid treatment in children with osteogenesis imperfecta. *Horm Res Paediatr*. 2011;75:346-353.
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9. Liu W, Lee B, Magamani SCS, et al. Approach to the patient: pharmacological therapies for fracture risk reduction in adults with osteogenesis imperfecta. *J Clin Endocrinol Metab*. 2023;108:1787-1796.
10. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 5.2026 – Janurary 23, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 3, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/13/2024
Annual Revision	**Treatment of Bone Loss in a Patient with Prostate Cancer Receiving Androgen Deprivation Therapy:** This was a new Condition of Approval that was added under Other Uses with Supportive Evidence. Dosing was also added.	03/19/2025
Annual Revision	No criteria changes.	03/18/2026