

Reclast® (zoledronic acid) Injection

When requesting Reclast® (zoledronic acid), the individual requiring treatment must be diagnosed with the one of the following FDA-approved indications or approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications

- Treatment and prevention of osteoporosis in postmenopausal women
- Treatment of osteoporosis in men
- Treatment and prevention of glucocorticoid-induced osteoporosis
- Paget's disease of bone

Approved Off-label Compendial use

- Osteogenesis imperfecta

Coverage Guidelines

Treatment of osteoporosis in men or postmenopausal women

The individual must meet **all** of the following criteria for approval:

- The individual is at high risk for fracture, defined as:
 - o History of osteoporotic (fragility) fracture;
 - o Current or past bone mineral density (BMD) T-score at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist); OR
 - o Current or past bone mineral density (BMD) T-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist) and the patient is at high risk of fracture; AND
- Meets at least one of the following conditions (not required with history of osteoporotic [fragility] fracture):
 - o Has failed or had an inadequate response to a 12-month trial of an oral bisphosphonate agent (e.g., alendronate, risedronate, etc.);
 - o Has tried an IV bisphosphonate agent (e.g., Boniva); OR
 - o Cannot tolerate (e.g., severe GI adverse effects) or is not a candidate for oral bisphosphonate agents due to an intolerance or contraindication (e.g., esophageal ulcers, cannot remain upright post-oral bisphosphonate therapy, cannot swallow oral medications).

Prevention of osteoporosis in postmenopausal women:

The individual must meet **all** of the following criteria for approval:

- The individual is at high risk for fracture, defined as:
 - o History of osteoporotic (fragility) fracture; OR

- o Current or past bone mineral density (BMD) T-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist); AND
- Meets at least one of the following conditions (not required with history of osteoporotic [fragility] fracture):
 - o Has failed or had an inadequate response to a 12-month trial of an oral bisphosphonate agent (e.g., alendronate, risedronate, etc.);
 - o Has tried an IV bisphosphonate agent (e.g., Boniva); OR
 - o Cannot tolerate (e.g., severe GI adverse effects) or is not a candidate for oral bisphosphonate agents due to an intolerance or contraindication (e.g., esophageal ulcers, cannot remain upright post-oral bisphosphonate therapy, cannot swallow oral medications).

For reauthorization, at least 24 months must have elapsed since the last dose.

Treatment and prevention of glucocorticoid-induced osteoporosis

The individual must meet **all** of the following criteria for approval:

- The individual is initiating or continuing systemic glucocorticoids (e.g., prednisone); AND
- Meets at least one of the following conditions:
 - o History of osteoporotic (fragility) fracture;
 - o Has failed or had an inadequate response to a 12-month trial of an oral bisphosphonate agent (e.g., alendronate, risedronate, etc.);
 - o Has tried an IV bisphosphonate agent (e.g., Boniva); OR
 - o Cannot tolerate (e.g., severe GI adverse effects) or is not a candidate for oral bisphosphonate agents due to an intolerance or contraindication (e.g., esophageal ulcers, cannot remain upright post-oral bisphosphonate therapy, cannot swallow oral medications).

Paget's disease of bone

The individual must meet at least one of the following criteria for approval:

- Has elevations in serum alkaline phosphatase of two times higher than the upper limit of the age-specific normal reference range;
- Is symptomatic (e.g., bone pain, hearing loss, osteoarthritis); OR
- Is at high risk for complications from their disease (e.g., immobilization, bone deformity, fractures, nerve compression syndrome).

Osteogenesis imperfecta

The individual with a diagnosis of osteogenesis imperfecta will receive approval for 12 months.

Approval Duration (Paget's disease of bone): 1 dose
Approval Duration (All other indications): 12 months

Dosing Recommendations

Treatment of osteoporosis in men or postmenopausal women

Approve up to a maximum dose of 5 mg, administered intravenously, no more frequently than once a year.

Prevention of osteoporosis in postmenopausal women

Approve up to a maximum dose of 5 mg, administered intravenously, no more frequently than once every two years.

Glucocorticoid-induced osteoporosis

Approve up to a maximum dose of 5 mg, administered intravenously, no more frequently than once a year.

Paget's disease of bone

Approve up to a maximum dose of 5 mg, administered intravenously, once.

Osteogenesis imperfecta

Approve up to a maximum dose of 0.05mg per kilogram, administered intravenously, no more frequently than once every 3 months.

References

1. Reclast® injection for intravenous infusion [prescribing information]. East Hanover, NJ: Novartis; July 2017.
2. Biggin A, Munns CF. Long-term bisphosphonate therapy in osteogenesis imperfect. *Curr Osteoporos Rep*. 2017;15(5):412-418.
3. 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.
4. 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.
5. Brown JJ, Zacharin MR. Safety and efficacy of intravenous zoledronic acid in paediatric osteoporosis. *J Pediatr Endocrinol Metab*. 2009;22(1):55-63.
6. Dwan K, Phillipi CA, Steiner RD, Basel D. Bisphosphonate therapy for osteogenesis imperfecta. *Cochrane Database Syst Rev*. 2016;10:CD005088.
7. Zoledronic Acid (Reclast®). In: DRUGDEX® System Micromedex. Greenwood Village, CO: Thompson Reuters (Healthcare) Inc. [Updated; August 21, 2019; Accessed August 29, 2019].