

Reclast® (zoledronic acid) Injection

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

FDA-approved Indications

Reclast is indicated for:

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

Approved Off-label Compendial Use

- Osteogenesis imperfecta

Coverage Guidelines

Treatment of osteoporosis in postmenopausal women or men

For an initial authorization:

An individual has had an osteoporotic fracture or a fragility fracture;

OR

An individual must meet **BOTH** of the following criteria for approval:

- Must have one of the following criteria:
 - Has had a T-score at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% radius (wrist) OR
 - Has low bone mass (T-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% radius [wrist] and is at high risk for fracture;

AND

- Must have one of the following criteria:
 - Has experienced inadequate efficacy with oral bisphosphonate therapy after a 12-month trial (e.g., ongoing and significant loss of bone mineral density [BMD], lack of BMD increase) OR
 - Has experienced significant intolerance to an oral bisphosphonate (e.g., severe gastrointestinal related adverse events) OR
 - Is unable to take an oral bisphosphonate due to one of the following conditions: 1) cannot swallow or has difficulty swallowing, 2) cannot remain in an upright position post oral bisphosphonate administration; 3) has a pre-existing gastrointestinal medical condition in which IV bisphosphonate therapy may be warranted (e.g., esophageal lesions, esophageal ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]).

For reauthorization:

An individual must have experienced at least one of the following with the use of Reclast:

- Stability;
- Reduction in vertebral fractures; OR
- Increase in bone mineral density.

Prevention of osteoporosis in postmenopausal women

For an initial authorization:

An individual has had an osteoporotic fracture or a fragility fracture;

OR

An individual must meet **BOTH** of the following criteria for approval:

- Has had a T-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% radius (wrist)

AND

- Must have one of the following criteria:
 - Has experienced inadequate efficacy with oral bisphosphonate therapy after a 12-month trial (e.g., ongoing and significant loss of bone mineral density [BMD], lack of BMD increase) OR
 - Has experienced significant intolerance to an oral bisphosphonate (e.g., severe gastrointestinal related adverse events) OR
 - Is unable to take an oral bisphosphonate due to one of the following conditions: 1) cannot swallow or has difficulty swallowing, 2) cannot remain in an upright position post oral bisphosphonate administration; 3) has a pre-existing gastrointestinal medical condition in which IV bisphosphonate therapy may be warranted (e.g., esophageal lesions, esophageal ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia])

For reauthorization:

An individual must meet **BOTH** of the following criteria for approval:

- Has experienced at least one of the following with the use of Reclast:
 - Stability;
 - Reduction in vertebral fractures; OR
 - Increase in bone mineral density;

AND

- At least 24 months must have elapsed since the last Reclast dose.

Treatment and prevention of glucocorticoid-induced osteoporosis

For an initial authorization:

An individual must meet **BOTH** of the following criteria for approval:

- Is initiating or continuing systemic glucocorticoids (e.g. prednisone);

AND

- Must have one of the following criteria:
 - Has experienced inadequate efficacy with oral bisphosphonate therapy after a 12-month trial (e.g., ongoing and significant loss of bone mineral density [BMD], lack of BMD increase) OR
 - Has experienced significant intolerance to an oral bisphosphonate (e.g., severe gastrointestinal related adverse events) OR
 - Is unable to take an oral bisphosphonate due to one of the following conditions: 1) cannot swallow or has difficulty swallowing, 2) cannot remain in an upright position post oral bisphosphonate administration; 3) has a pre-existing gastrointestinal medical condition in which IV bisphosphonate therapy may be warranted (e.g., esophageal lesions, esophageal ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]) OR
 - Has had an osteoporotic fracture or a fragility fracture.

For reauthorization:

An individual must meet **BOTH** of the following criteria:

- Is continuing systemic glucocorticoids (e.g. prednisone);

AND

- Has experienced at least one of the following with the use of Reclast:
 - Stability;
 - Reduction in vertebral fractures; OR
 - Increase in bone mineral density.

Paget's disease of bone

The individual must meet **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 OR
- 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/Glucocorticoid-induced osteoporosis

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

Prevention of osteoporosis in postmenopausal women

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

Paget's disease of bone

The recommended dose is 5 mg infusion.

Osteogenesis imperfecta

Dosing information is limited. Approve up to a maximum dose of 0.05 mg/kg administered intravenously, no more frequently than once every 3 months.

References

1. Reclast® injection [prescribing information]. East Hanover, NJ: Novartis; April 2020.
2. Biggin A, Munns CF. Long-term bisphosphonate therapy in osteogenesis imperfecta. *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. Vuorimies I, Toiviainen-Salo S, Hero M, Makitie O. Zoledronic acid treatment in children with osteogenesis imperfecta. *Horm Res Paediatr.* 2011;75:346-353.
7. Dwan K, Phillipi CA, Steiner RD, Basel D. Bisphosphonate therapy for osteogenesis imperfecta. *Cochrane Database Syst Rev.* 2016;10:CD005088.