

Reclast® (zoledronic acid) Injection

When requesting Reclast® (zoledronic acid), the individual requiring treatment must be diagnosed with the following FDA-approved indications or approved compendial uses 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
- Glucocorticoid-induced osteoporosis
- Paget's disease of bone

Approved Off-label Compendial uses

None

Coverage Guidelines

For all indications, the individual meets the following safety criteria for approval:

- The individual has a serum calcium or corrected calcium greater than the lower limit of normal per laboratory reference.
- Does not have creatinine clearance less than 35 mL/min
- Does not have evidence of acute renal impairment

Treatment of osteoporosis in a man or postmenopausal woman:

- The individual is at high risk for fracture, defined as one of the following:
 - History of an osteoporotic (fragility) fracture
 - Multiple risk factors for fracture** AND a baseline bone mineral density (BMD) T-score by DXA (dual-energy x-ray absorptiometry) of less than or equal to -2.5
 - FRAX® 10-year fracture probability of greater than or equal 20% or hip fracture probability of greater than or equal to 3% AND a baseline BMD T-score by DXA of less than or equal to -2.5
- The individual has had an inadequate response, contraindication or intolerance to an oral bisphosphonate agent (eg, alendronate, risedronate, etc.) unless history of osteoporotic (fragility) fracture is present.

Prevention of osteoporosis in a postmenopausal woman:

- The individual meets one of the following criteria for approval:
 - Individual has multiple risk factors for fracture** AND a baseline BMD T-score by DXA between -1 and -2.5
 - FRAX® 10-year fracture probability of greater than or equal to 20% or hip fracture probability of greater than or equal to 3%⁸ AND a baseline BMD T-score by DXA between -1 and -2.5

- The individual has had an inadequate response, contraindication or intolerance to an oral bisphosphonate agent (eg, alendronate, risedronate, etc.)

Glucocorticoid-induced osteoporosis:

- For a man or postmenopausal woman greater than or equal to 50 years of age receiving glucocorticoid therapy, he/she has a high risk for fracture defined as:
 - A history of an osteoporotic (fragility) fracture, a FRAX® 10-year fracture probability of greater than or equal to 20% or hip fracture probability of greater than or equal to 3% plus a baseline BMD T-score by DXA of less than or equal to -2.5, OR has an overall high clinical risk profile (eg, low BMI, parental history of hip fracture, smoker, greater than or equal to 3 alcoholic drinks per day, higher daily and/or cumulative glucocorticoid dose, etc.)
 - The individual has had an inadequate response, contraindication or intolerance to an oral bisphosphonate agent (eg, alendronate, risedronate, etc.) unless history of osteoporotic (fragility) fracture is present.
- For a man or postmenopausal woman greater than or equal to 50 years of age receiving glucocorticoid therapy, he/she has a medium to low fracture risk (eg, FRAX® 10-year fracture probability of greater than or equal to 20% or hip fracture probability of greater than or equal to 3%)
 - The individual's glucocorticoid dose is greater than 7.5 mg/day of prednisone or its equivalent
 - AND the individual has had an inadequate response, contraindication or intolerance to an oral bisphosphonate agent (eg, alendronate, risedronate, etc.)
- For a man or premenopausal woman of non-childbearing potential less than 40 years of age receiving glucocorticoid therapy, he/she will be taking greater than 7.5 mg/day of prednisone or its equivalent for at least 6 months and meets one of the following criteria for approval:
 - Rapid bone loss (10% or greater hip or spine over 1 year) and the individual has had an inadequate response, contraindication or intolerance to an oral bisphosphonate agent (eg, alendronate, risedronate, etc.)
 - Hip or spine BMD Z score less than -3 and the individual has had an inadequate response, contraindication or intolerance to an oral bisphosphonate agent (eg, alendronate, risedronate, etc.)

Paget's disease of bone:

- The individual meets at least one of the following criteria for approval:
 - The individual has elevations of serum alkaline phosphatase of greater than or equal to 2x ULN of the age-specific normal range
 - The individual is symptomatic
 - The individual is at risk for complications from their disease
- For initial treatment, approve for a single dose
- For retreatment:
 - The individual meets at least one of the following criteria for retreatment:
 - The individual has relapsed based on increases in serum alkaline phosphatase
 - The individual has failed to achieve normalization of serum alkaline phosphatase

- o The individual is symptomatic
- Approve for a single dose

Approval Duration: 12 months

**** Risk factors for fracture include:** a prior fragility fracture, parental history of hip fracture, current tobacco smoking, secondary causes of osteoporosis (e.g., rheumatoid arthritis, hypogonadism, use of phenytoin, phenobarbital, long term warfarin, etc.), daily alcohol use of three or more drinks per day, advanced age (greater than 65), body habitus (weight less than 127 lbs or BMI less than or equal to 20), Caucasian or Asian race, sedentary lifestyle, diet deficient in calcium or vitamin D without adequate supplementation, long-term use of corticosteroids (defined as greater than 3 continuous months), early menopause, etc. *(Please note: this list is not all-inclusive)*

Dosing Information

- For treatment of osteoporosis in men or postmenopausal women: 5 mg infusion given once a year.
- For prevention of osteoporosis in postmenopausal women: 5 mg infusion given once every two years.
- For glucocorticoid-induced osteoporosis: 5 mg infusion given once a year.
- For treatment of Paget's disease of bone: a single 5 mg infusion.

References

1. Reclast prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corporation: April 2016. Accessed February 23, 2018.
2. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014. Accessed February 23, 2018.
3. Camacho PM, Petak SM, et al. AACE medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract. 2016; 22 Suppl 4. Accessed February 23, 2018.
4. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2012 Jun; 97(6):1802-1822. Accessed February 23, 2018.
5. Buckley, L., Guyatt, G., et al. American College of Rheumatology 2017 recommendations for the prevention and treatment of glucocorticoid-induced osteoporosis. Arthritis Care Res. 2017 Aug; 69(8) 1521-1537. Accessed February 23, 2018.
6. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed February 23, 2018.
7. Florence R, Allen S, Benedict L, et al. Institute for Clinical Systems Improvement. Health care guideline: Diagnosis and treatment of osteoporosis. Eighth Edition. July 2013. Accessed February 23, 2018.
8. World Health Organization. FRAX® WHO fracture risk assessment tool. Available at: <https://www.shef.ac.uk/FRAX/>. Accessed February 23, 2018.