

Reclast® (zoledronic acid) Injection J3489

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 indications¹

Reclast® (zoledronic acid)

- Treatment and prevention of osteoporosis in postmenopausal women¹
- Treatment of osteoporosis in men¹
- Glucocorticoid-induced osteoporosis¹
- Paget's disease of bone¹

Approved Off-label Compendial uses

- No off-label uses meet evidence standards⁶

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.¹
- Does not have creatinine clearance < 35 mL/min¹
- Does not have evidence of acute renal impairment¹

Treatment of osteoporosis in a man or postmenopausal woman¹:

- The individual is at high risk for fracture, defined as one of the following:
 - History of an osteoporotic (fragility) fracture¹
 - Multiple risk factors for fracture^{**2,3,7} AND a baseline bone mineral density (BMD) T-score by DXA (dual-energy x-ray absorptiometry) of ≤ -2.5 ¹
 - FRAX® 10-year fracture probability of $\geq 20\%$ or hip fracture probability of $\geq 3\%$ ⁸ AND a baseline BMD T-score by DXA of ≤ -2.5 ¹
- AND the individual has had an inadequate response, contraindication or intolerance to an oral bisphosphonate agent (eg, alendronate, risedronate, etc.)

Prevention of osteoporosis in a postmenopausal woman¹:

- The individual meets one of the following criteria for approval:
 - Individual has multiple risk factors for fracture^{**2,3,7} AND a baseline BMD T-score by DXA between -1 and -2.5 ^{2,3}
 - FRAX® 10-year fracture probability of $\geq 20\%$ or hip fracture probability of $\geq 3\%$ ⁸ AND a baseline BMD T-score by DXA between -1 and -2.5 ^{2,3}
- AND the individual has had an inadequate response, contraindication or intolerance to an oral bisphosphonate agent (eg, alendronate, risedronate, etc.)

Glucocorticoid-induced osteoporosis¹:

- For a man or postmenopausal woman ≥ 50 years of age receiving glucocorticoid therapy, he/she has a high risk for fracture defined as⁵:
 - A history of an osteoporotic (fragility) fracture, a FRAX[®] 10-year fracture probability of $\geq 20\%$ or hip fracture probability of $\geq 3\%$ plus a baseline BMD T-score by DXA of ≤ -2.5 , OR has an overall high clinical risk profile (eg, low BMI, parental history of hip fracture, smoker, ≥ 3 alcoholic drinks per day, higher daily and/or cumulative glucocorticoid dose, etc.)⁵
 - AND the individual has had an inadequate response, contraindication or intolerance to an oral bisphosphonate agent (eg, alendronate, risedronate, etc.)
- For a man or postmenopausal woman ≥ 50 years of age receiving glucocorticoid therapy, he/she has a medium to low fracture risk (eg, FRAX[®] 10-year fracture probability of $\geq 20\%$ or hip fracture probability of $\geq 3\%$)⁵
 - The individual's glucocorticoid dose is ≥ 7.5 mg/day of prednisone or its equivalent⁵
 - 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 < 50 years of age receiving glucocorticoid therapy, he/she has a history of an osteoporotic (fragility) fracture and meets one of the following criteria for approval:⁵
 - The anticipated duration of glucocorticoid therapy is > 3 months and the individual has had an inadequate response, contraindication or intolerance to an oral bisphosphonate agent (eg, alendronate, risedronate, etc.)
 - The anticipated duration of glucocorticoid therapy is 1-3 months and the glucocorticoid dose is ≥ 7.5 mg/day of prednisone or its equivalent⁵ and the individual has had an inadequate response, contraindication or intolerance to an oral bisphosphonate agent (eg, alendronate, risedronate, etc.)

Paget's disease of bone¹:

- The individual meets at least one of the following criteria for approval¹:
 - The individual has elevations of serum alkaline phosphatase of $\geq 2x$ ULN of the age-specific normal range¹
 - The individual is symptomatic¹
 - The individual is at risk for complications from their disease¹
- For initial treatment, approve for a single dose¹
- For retreatment:¹
 - The individual meets at least one of the following criteria for retreatment¹:
 - The individual has relapsed based on increases in serum alkaline phosphatase¹
 - The individual has failed to achieve normalization of serum alkaline phosphatase¹
 - The individual is symptomatic¹
 - Approve for a single dose¹

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)

Additional Information for Prescribers

- For osteoporosis, optimal duration of use has not been determined. For individuals at low-risk for fracture, consider drug discontinuation after 3 to 5 years of use.¹
- For treatment of osteoporosis in men or postmenopausal women, a 5 mg infusion is given once a year.¹
- For prevention of osteoporosis in postmenopausal women, a 5 mg infusion is given once every two years.¹
- For glucocorticoid-induced osteoporosis, a 5 mg infusion is given once a year.
- For treatment of Paget's disease of bone, a 5 mg infusion is given as a single treatment.¹ Retreatment maybe indicated in individuals who have relapsed, based on increases in serum alkaline phosphatase, or in those who failed to achieve normalization of their serum alkaline phosphatase, or in those with symptoms, as dictated by medical practice.¹

References

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