

Prolia® (denosumab)

When requesting Prolia® (denosumab) for non-oncology indications, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Non-oncology Indications

Treatment of postmenopausal women with osteoporosis at high risk for fracture

Prolia is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Treatment to increase bone mass in men with osteoporosis

Prolia is indicated for treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Treatment of glucocorticoid-induced osteoporosis

Prolia is indicated for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months.

Coverage Guidelines

Treatment of osteoporosis in postmenopausal women and men

For an initial authorization:

The individual must meet the following criteria for approval:

- Meets one of the following:
 - Had an osteoporotic fracture or a fragility fracture; OR
 - 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 fractures)
- Meets one of the following:
 - Has experienced inadequate efficacy with an oral bisphosphonate therapy after a 12-month trial (e.g., ongoing and significant loss of bone mineral density [BMD], lack of BMD increase, an osteoporotic fracture or a fragility fracture); OR

- Has experienced significant intolerance to an oral bisphosphonate (e.g., severe gastrointestinal related adverse events, severe musculoskeletal-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 tried IV bisphosphonate agent (e.g., ibandronate injection [Boniva], zoledronic acid injection [Reclast]); OR
- Had an osteoporotic fracture or a fragility fracture; OR
- Has advanced chronic kidney disease (CrCL < 30 mL/min).
- For patients with advanced chronic kidney disease (CrCL < 30 mL/min), the presence of mineral and bone disorder (MBD) has been evaluated to reduce the risk of Prolia-induced hypocalcemia.

For reauthorization:

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

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

Treatment of glucocorticoid-induced osteoporosis

For an initial authorization

The individual must meet the following criteria for approval:

- Is initiating or continuing systemic glucocorticoids (e.g., prednisone);
- Meets one of the following:
 - Has tried zoledronic acid injection (Reclast); OR
 - Has experienced inadequate efficacy with an oral bisphosphonate therapy after a 12-month trial (e.g., ongoing and significant loss of bone mineral density [BMD], lack of BMD increase, an osteoporotic fracture or a fragility fracture); OR
 - Has experienced significant intolerance to an oral bisphosphonate (e.g., severe gastrointestinal related adverse events, severe musculoskeletal-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
 - Had an osteoporotic fracture or a fragility fracture; OR
 - Has advanced chronic kidney disease (CrCL < 30 mL/min).
- For patients with advanced chronic kidney disease (CrCL < 30 mL/min), the presence of mineral and bone disorder (MBD) has been evaluated to reduce the risk of Prolia-induced hypocalcemia.

For reauthorization:

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

- Is continuing systemic glucocorticoids (e.g. prednisone);
- Has experienced at least one of the following with the use of Prolia:
 - Stability; OR
 - Reduction in vertebral fractures; OR
 - Increase in bone mineral density.

Approval duration: 12 months

Dosing Recommendation

The recommended dose is 60 mg administered as a single subcutaneous injection once every 6 months.

References

1. Prolia® injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; March 2024.
2. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2019;104(5):1595-1622. Available at: <https://www.endocrine.org/guidelines-and-clinical-practice/clinical-practice-guidelines/osteoporosis-in-postmenopausal-women>. Accessed on , March 10, 2025.
3. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis-2020 update. *Endocrin Pract.* 2020;26(Suppl 1):1-46. Available at: [https://pro.aace.com/sites/default/files/2020-05/Vol%2026%20Supplement%201%20\(May%202020\)%20GL-2019-0524_0.pdf](https://pro.aace.com/sites/default/files/2020-05/Vol%2026%20Supplement%201%20(May%202020)%20GL-2019-0524_0.pdf). Accessed on March 10, 2025.
4. Buckley L, Guyatt G, Fink HA, et al. 2017 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. *Arthritis Rheumatol.* 2017;69(8):1521-1537. Available at: <https://www.rheumatology.org/Portals/0/Files/Guideline-for-the-Prevention-and-Treatment-of-GIOP.pdf>. Accessed on March 10, 2025.
5. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporosis Int.* 2022;33(10):2049-2102.

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