CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs
Prolia® (denosumab)

Effective: January 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Osteoporosis—the most common bone disorder affecting humans—is a generalized skeletal disorder characterized by compromised bone strength, predisposing a person to an increased risk of fracture, most importantly of the spine and hip. Several drugs with differing mechanisms of action have demonstrated the ability to prevent bone loss in postmenopausal women and to reduce fracture risk in women with postmenopausal osteoporosis. The mechanisms of action of all osteoporosis drugs are to modulate (either to inhibit or to activate) bone metabolism. Denosumab may be considered in patients who are unable to use oral therapy, prefer to avoid intravenous bisphosphonates due to side effects, or have impaired renal function, and as initial therapy for patients at very high fracture risk (defined as a recent fracture [e.g. within the past 12 months], fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm [e.g. long-term glucocorticoids], very low T-score (e.g. less than -3.0), high risk for falls or history of injurious falls, and very high fracture probability by Fracture Risk Assessment Tool [FRAX]).

Approval of Prolia for the treatment of postmenopausal woman with osteoporosis was based on a three-year placebo-controlled trial, in which treatment with Prolia significantly reduced the incidence of new morphometric vertebral fractures at 1, 2, and 3 years. Incidence of new vertebral fractures at year 3 was 7.2% in patients treated with placebo compared to 2.3% in patients treated with Prolia. The absolute risk reduction was 4.8% and relative risk reduction was 68% for new morphometric vertebral fractures at year 3.

Approval of Prolia to increase bone mass in men with osteoporosis at high risk for fracture was based on a one-year placebo-controlled trial in which treatment with Prolia significantly increased bone mineral density at one year. Treatment differences favoring Prolia in bone mineral density at 1-year were 4.8% at the lumbar spine, 2.0% at the total hip, and 2.2% at femoral neck.

Approval of Prolia for the treatment of glucocorticoid-induced osteoporosis was based on a 12-month primary analysis of a two-year clinical trial. Patients treated with Prolia achieved a significant increase in lumbar spine bone mineral density compared to patients treated with oral bisphosphonate therapy.

Approval of Prolia for the treatment of bone loss in men with nonmetastatic prostate cancer receiving androgen deprivation therapy was based on a three-year placebo-controlled trial. The primary endpoint was percent change in lumbar spine bone mineral density from baseline at month 24 which significantly favored treatment with Prolia over placebo (treatment difference of 6.7%).

Approval of Prolia for the treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer was based on a two-year placebo-controlled trial. The primary endpoint was percent change in lumbar spine bone mineral density from baseline to month 12 which significantly favored treatment with Prolia over placebo (treatment difference, 5.5%).

Food and Drug Administration-Approved Indications

Prolia (denosumab) is a RANK ligand inhibitor indicated for the:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast

cancer

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Prolia for Members when the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. The member is at high risk of fracture defined as a history of osteoporotic fracture or multiple risk factors for fracture and a T score less than or equal to -2.0 as evidenced via bone density scan
    b. The member is a female at high risk for fracture due to adjuvant aromatase inhibitor therapy for breast cancer and is using Prolia as a treatment to increase bone mass
    c. The member is a male at high risk of fracture due to androgen deprivation therapy for non-metastatic prostate cancer
    d. The member is being treated for glucocorticoid-induced osteoporosis and is at high risk for fracture

Limitations

- Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0897	Injection, denosumab, 1mg

References

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of postmenopausal women with low BMD. J Bone Miner Res 2007; 22:1832-41.
15. McClung MR, Lewiecki EM, Cohen SB, et al. Denosumab in postmenopausal women with low bone mineral density. N Eng J Med 2006; 354:821-31.
16. National Osteoporosis Foundation. Prevalence Report. Available at: nof.org/print/219. Accessed October 4, 2012. Prolia® (denosumab) 5
17. NIH Osteoporosis and Related Bone Diseases National Resource Center, Osteoporosis in Men. Available at: niams.nih.gov/Health_Info/Bone/Osteoporosis/men.asp. Accessed October 4, 2012.
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Approval And Revision History

June 13, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)
- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: April 2023 added Medical Benefit Drugs to title and CPCT logo update
- May 17, 2023: Annual review, no change, effective July 1, 2023
- September 12, 2023: Removed the Limitation The Plan will not authorize coverage of Prolia for any indication(s) other than those which are FDA-approved. Added the Limitation Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements (effective 1/1/2024).
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.