CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs
Prolia® (denosumab)

Effective: October 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 is commonly diagnosed via a dual energy x-ray absorptiometry (DXA) scan that characterizes bone density and compares with normal values for health young adults of the same sex. From this comparison, a "T-score" is derived based on the number of standard deviations (SD) an individual falls above or below the young adult mean. The World Health Organization recommends use of the Fracture Risk Assessment Tool (FRAX) to determine an individual's 10-year probability of a major osteoporotic fracture based on risk factors including age, sex, weight, height, personal or family history of fracture, smoking, alcohol intake, glucocorticoid use, comorbid conditions, and bone mineral density (BMD). Using the DXA score and FRAX probability, a decision on when to initiate pharmacotherapy is made. Pharmacotherapy is generally recommended for patients with a history of a fragility fracture at the hip or spine, a T-score ≤ −2.5, or a T-score between −1 and −2.5 and a 10-year probability for a major osteoporosis-related fracture of 20% or more or a 10-year probability of hip fracture ≥3%. A stepwise approach is often followed in disease management.

Using the DXA score and FRAX probability, clinicians determine when to initiate pharmacotherapy. Numerous brand and generic pharmacotherapies are marketed to treat osteoporosis via varied mechanisms. Initiation of pharmacotherapy is generally recommended for patients with a history of a fragility fracture at the hip or spine, a T-score ≤ −2.5, or a T-score between −1 and −2.5 and a 10-year probability for a major osteoporosis-related fracture of 20% or more or a 10-year probability of hip fracture ≥3%. Lacking robust head-to-head efficacy data, a stepwise approach is often chosen in disease management. Choice of therapy should be based upon level of fracture risk, efficacy, safety, cost, convenience, and other patient-related factors.

Denosumab may be considered in patients who are unable to use oral therapy, prefer to avoid intravenous (IV) bisphosphonates due to side effects, or have impaired renal function, and as initial therapy for patients at very high fracture risk (defined as as 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 FRAX).

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 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 by one (1) of the following:
        i. History of one or more osteoporotic fracture
        ii. T-score of less than or equal to -1.0 and greater than -2.5 and the prescriber determines the Member is at high risk for fracture
        iii. T-score less than or equal to -2.5
        iv. FRAX score of 10-year risk of major osteoporotic fracture greater than or equal to 20% or a risk of hip fracture greater than or equal to 3%
    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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2. Boonen S, Adachi JD, Cummings SR, et al. Treatment with denosumab reduces the incidence of new vertebral and hip fractures in postmenopausal women at high risk. J Clin Endocrinol Metab 2011; 96:1727-36.
3. Brown JP, Prince RL, Deal C et al. Comparison of the effect of denosumab and alendronate on bone mineral density and biochemical markers of bone turnover in postmenopausal women with low bone mass: a randomized, blinded, phase 3 trial. J Bone Miner Res. 2009 Jan; 24(1):153-61.
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6. Dore RK, Cohen SB, Lane NE, et al. Effects of denosumab on bone mineral density and bone turnover in patients with rheumatoid arthritis receiving concurrent glucocorticoids or bisphosphonates. Ann Rheum Dis 2010;69:872-5.
7. Hu MI, Glezerman I, Leboulleux S, et al. Denosumab for patients with persistent or relapsed hypercalcemia of malignancy despite recent bisphosphonate treatment. J Natl Cancer Inst. 2013 Sep 18;105(18):1417-20.
8. Hu MI, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. J Clin Endocrinol Metab. 2014 Sep;99(9):3144-52.
9. Kendler DL, Roux C, Benhamou CL, et al. Effects of denosumab on bone mineral density and bone turnover in postmenopausal women transitioning from alendronate therapy. J Bone Miner Res 2010; 25:72-81.
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12. Lewiecki EM. Denosumab- an emerging treatment for postmenopausal osteoporosis. Expert Opinion Biol Ther. 2010 Mar; 10(3): 467-76.

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15. National Osteoporosis Foundation. Prevalence Report. Available at: nof.org/print/219. Accessed October 4, 2012. Prolia® (denosumab) 5
16. 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.
17. North American Menopause Society. Management of osteoporosis in postmenopausal women: 2010 Position statement of the North American Menopause Society. Menopause. 2010 Jan-Feb; 17(1): 25-54.
18. Prolia (denusomab) [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2024.
19. Roux C, Hofbauer LC, Ho PR, et al. Denosumab compared with risedronate in postmenopausal women suboptimally adherent to alendronate therapy: efficacy and safety results from a randomized open-label study. Bone. 2014 Jan;58:48-54.
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Approval And Revision History

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

May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC).

Subsequent endorsement date(s) and changes made:

- 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.
- August 13, 2024: Expanded the definition of high risk for fracture (eff 10/1/24).
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24)

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 guidelines 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.