Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

# Prolia® (denosumab) and Biosimilars

*Effective: January 1, 2026*

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|---|---|
| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☐ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Public Plans Products**

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

**Senior Products**

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 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

**Bildyos (denosumab-nxxp), Bosaya (denosumab-kyqq), Conexxence (denosumab-bnht), Jubbonti (denosumab-bbdz)** and **Stoboclo (denosumab-bmwo)** are biosimilars to Prolia.

## Clinical Guideline Coverage Criteria

The plan may authorize coverage of Prolia, Bildyos, Bosaya, Conexxence, Jubbonti, or Stoboclo 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 |
| Q5136 | Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg |
| Q5157 | Injection, denosumab-bmwo (stoboclo/osenvelt), biosimilar, 1 mg |
| Q5158 | Injection, denosumab-bnht (bomyntra/conexxence), biosimilar, 1 mg |

## References


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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.
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19. Bildyos (denosumab-nxxp) [package insert]. Jersey City, NJ: Organon & Co.; August 2025.
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21. Conexxence (denosumab-bnht) [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2025.
22. Jubbonti (denosumab-bbdz) [package insert]. Princeton, NJ: Sandoz Inc.; December 2024.
23. Stoboclo (denosumab-bmwo) [package insert]. Jersey City, NJ: Celltrion USA, Inc.; September 2025.
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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
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- 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)
- June 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: Added Bildyos (denosumab-nxxp), Bosaya (denosumab-kyqq), Conexxence (denosumab-bnht), Jubbonti (denosumab-bbdz) and Stoboclo (denosumab-bmwo) to the Medical Necessity Guideline (MNG). Updated name of MNG to Prolia® (denosumab) and Biosimilars (eff 1/1/26).
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/26).

## 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.