Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Xgeva® (denosumab) and Biosimilars

Effective: January 1, 2026

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

Applies to:

Commercial Products

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

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

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

Approval of Xgeva for the prevention of skeletal-related events in patients with bone metastases from solid tumors was demonstrated in three noninferiority trials comparing treatment with zoledronic acid. Treatment with Xgeva delayed the time to first skeletal-related event following randomization as compared to zoledronic acid in patients with breast or castrate-resistant cancer with osseous metastases. In patients with bone metastasis due to other solid tumors or lytic lesions due to multiple myeloma, Xgeva was noninferior to zoledronic acid in delaying the time to first skeletal-related event following randomization. Overall survival and progression-free survival were similar between arms in all three trials.

Approval of Xgeva for the prevention of skeletal-related events in newly diagnosed multiple myeloma patients with treatment through disease progression was also demonstrated in a noninferiority trial comparing treatment with zoledronic acid. Treatment with Xgeva was noninferior to zoledronic acid in delaying the time to first skeletal-related event following randomization. The results for overall survival were comparable between Xgeva and zoledronic acid treatment.

Approval of Xgeva for the treatment of giant cell tumor of bone in adults or skeletally mature adolescents was demonstrated in two open-label trials. The primary efficacy outcome measure was objective response rate using Response Evaluation Criteria in Solid Tumors (RECIST) v 1.1. The overall objective response rate (RECIST 1.1) was 25%.

Approval of Xgeva for the treatment of hypercalcemia of malignancy was demonstrated in an open-label, single-arm trial of patients who are refractory to treatment with intravenous bisphosphonate therapy. Over sixty (63.6%) of patients responded to treatment defined as corrected serum calcium ≤11.5 mg/dL (2.9 mmol/L), within 10 days after drug administration.

Food and Drug Administration-Approved Indications

Xgeva (denosumab) is a RANK ligand (RANKL) inhibitor indicated for:

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

Aukelso (denosumab-kyqq), Bilprevda (denosumab-nxxp), Bomyntra (denosumab-bnht), **Osenvelt (denosumab-bmwo)** and **Wyost (denosumab-bbdz)** are biosimilars to Xgeva.

***Note**: Providers and Members enrolled with Tufts Medicare Preferred may reference the TMP/OncoHealth guideline.*

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Xgeva, Aukelso, Bilprevda, Bomyntra, Osenvelt, or Wyost for Members when all the following criteria is met:

1. Documentation of **one (1)** of the following:
    a. Documented diagnosis of multiple myeloma or bone metastases from solid tumors AND Xgeva is being prescribed for the prevention of skeletal-related events
    b. Documented diagnosis of unresectable giant cell tumor of bone or surgical resection of giant cell tumor of bone is likely to result in severe morbidity
    c. Documented diagnosis of hypercalcemia of malignancy

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
Q5161	Injection, denosumab-kyqq (aukelso/bosaya), biosimilar, 1 mg
Q5162	Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 1 mg

References

1. Billing and Coding: Denosumab (Prolia, Xgeva). Center for Medicare and Medicaid Local Coverage Article (LCA) A53329. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52399&ver=45&.
2. Branstetter DG, Nelson SD, Manivel JC, et al. Denosumab induces tumor reduction and bone formation in patients with giant-cell tumor of bone. Clin Cancer Res. 2012 Aug 15; 18(16):4415- 24.
3. Diel IJ, Body JJ, Stopeck AT, Vadhan-Raj S, Spencer A, et al. The role of denosumab in the prevention of hypercalcaemia of malignancy in cancer patients with metastatic bone disease. Eur J Cancer. 2015 Jul;51(11):1467-75.
4. Ellis GK, Bone HG, Chlebowski R, Paul D, Spadafora S, et al. Randomized trial of denosumab in patients receiving adjuvant aromatase inhibitors for nonmetastatic breast cancer. J Clin Oncol 2008; 26:4875-4882.
5. 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.
6. Smith MR, Egerdie B, Toriz NH, et al. Denosumab in men receiving androgen-deprivation therapy for prostate cancer. N Eng J Med 2009;361-745-55.
7. Thomas D, Henshaw R, Skubitz K, et al. Denosumab in patients with giant-cell tumor of bone: an open-label, phase 2 study. Lancet Oncol. 2010 Mar; 11(3):275-80.
8. von Moos R, Body JJ, Egerdie B, et al. Pain and health-related quality of life in patients with advanced solid tumors and bone metastases: integrated results from three randomized, double- blind studies of denosumab and zoledronic acid. Support Care Cancer. 2013 Dec;21(12):3497- 507.
9. Xgeva (denosumab) [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020.
10. Wyost (denosumab-bbdz) [prescribing information]. Princeton, NJ: Sandoz Inc; March 2024.
11. Osenvelt (denosumab-bmwo) [prescribing information]. Jersey City, NJ: Celltrion USA, Inc; February 2025.
12. Bomyntra (denosumab-bnht) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA LLC; March 2025.
13. Bilprevda (denosumab-nxxp) [package insert]. Jersey City, NJ: Organon & Co.; August 2025.
14. Aukelso (denosumab-kyqq) [package insert]. Cambridge, MA: Biocon Biologics Inc.; September 2025.

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, updated MATogether and RITogether fax numbers to 617-673-0939
- 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: Updated the title of the MNG from Xgeva® (denosumab) for subcutaneous injection to Xegeva® (denosumab). Minor wording updates to clarify coverage. 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. Removed the following from use for hypercalcemia of malignancy "refractory to bisphosphonate therapy." (effective 1/1/2024).
- November 2023: Administrative Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- August 13, 2024: No changes (eff 10/1/24).
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: Added Aukelso, Bilprevda, Bomyntra, Osenvelt, and Wyost to the Medical Necessity Guideline (MNG). Updated the title to Xgeva (denosumab) and Biosimilars. Removed Tufts Medicare Preferred HMO and PPO from the MNG as coverage is carved out to OncoHealth (eff 1/1/26).
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/26).
- April 2026: Administrative update: Removed Carelink from template. Updated J codes for Aukeluso/Bosaya (Q5161) and Bildyos/Bilprevda (Q5162), effective 4/1/26.

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 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.