denosumab (Bomyntra-Osenvelt-Xgeva-Wyost)

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

Drug Details

USP Category: ANTINEOPLASTICS
Mechanism of Action: a monoclonal antibody that inhibits RANK ligand activity and prevents osteoclast formation, leading to decreased bone resorption and increased bone mass
HCPCS:
C9399, J3490, J3590: Injection, denosumab-bmwo (Osenvelt):
C9399, J3490, J3590: Injection, denosumab-bnht (Bomyntra):
J0897:Injection, denosumab, 1 mg
Q5136:Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg
How Supplied:
120 mg/1.7 mL (70 mg/mL) solution in a single-dose vial

Condition(s) listed in policy (see coverage criteria for details)

- Hypercalcemia of Malignancy, Refractory
- Prevention of Skeletal Related Events in Bone Metastases
- Prevention of Skeletal Related Events in Multiple Myeloma
- Treatment of Giant Cell Tumor of Bone

Any request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice:

Hypercalcemia of Malignancy, Refractory
Meets medical necessity if all the following are met:

1. Diagnosis of hypercalcemia of malignancy
2. Inadequate response, intolerance, or contraindication to intravenous bisphosphonate therapy given 7 to 30 days prior to the initiation of Xgeva (denosumab)
3. Request for Bomyntra, Osenvelt, or Xgeva: ***Effective 1/1/2026 and after***, will require an intolerable side effect or contraindication with preferred denosumab product (i.e. Wyost) that is not expected with the requested drug

Covered Doses:
120 mg given subcutaneously on Day 1, and repeated 1, 2, and 4 weeks later, then every 4 weeks thereafter

Coverage Period:
yearly

ICD-10:
E83.52

Prevention of Skeletal Related Events in Bone Metastases
Meets medical necessity if all the following are met:
1. Diagnosis of bone metastases from solid tumors
2. Documentation of metastatic bone disease by scan or x-ray
3. Request for Bomyntra, Osenvelt, or Xgeva: ***Effective 1/1/2026 and after***, will require an intolerable side effect or contraindication with preferred denosumab product (i.e. Wyost) that is not expected with the requested drug

Covered Doses:
120 mg given subcutaneously every 4 weeks

Coverage Period:
yearly

ICD-10:
C79.51, C79.52

Prevention of Skeletal Related Events in Multiple Myeloma
Meets medical necessity if all the following are met:
1. Request for Bomyntra, Osenvelt, or Xgeva: ***Effective 1/1/2026 and after***, will require an intolerable side effect or contraindication with preferred denosumab product (i.e. Wyost) that is not expected with the requested drug

Covered Doses:
120 mg given subcutaneously every 4 weeks

Coverage Period:
yearly

ICD-10:
C90.00, C90.01, C90.02

Treatment of Giant Cell Tumor of Bone

Meets medical necessity if all the following are met:

1. Patient is > 18 years of age OR an adolescent whose bones have matured
2. Tumor is unresectable, metastatic, recurrent, or resectable with unacceptable morbidity
3. Request for Bomyntra, Osenvelt, or Xgeva: ***Effective 1/1/2026 and after***, will require an intolerable side effect or contraindication with preferred denosumab product (i.e. Wyost) that is not expected with the requested drug

Covered Doses:
120 mg given subcutaneously on Day 1, and repeated 1, 2, and 4 weeks later, then every 4 weeks thereafter

Coverage Period:
yearly

ICD-10:
D48.0

Additional Information

Summary of Evidence

The contents of this policy were created after examining the following resources:

1. The prescribing information for Xgeva, Wyost, Osenvelt, and Bomyntra
2. CMS approved compendium in accordance with the accepted compendia ratings listed:
   a. Micromedex DrugDex - Class I, Class IIa, of Class IIb
   b. American Hospital Formulary Service-Drug Information (AHFS-DI) - supportive narrative text
   c. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium - Category 1 or 2A
   d. Lexi-Drugs – "Use: Off-Label" and rated as "Evidence Level A" (cancer indications only)
   e. Clinical Pharmacology - supportive narrative text (cancer indications only)
3. Noridian Healthcare Solutions Medicare: Drugs, Biologics and Injections
4. NCCN Guideline: Bone Cancer
5. NCCN Guideline: Breast Cancer
6. NCCN Guideline: Kidney Cancer
7. NCCN Guideline: Multiple Myeloma
8. NCCN Guideline: Non-Small Cell Lung Cancer
9. NCCN Guideline: Prostate Cancer
10. NCCN Guideline: Systemic Mastocytosis
11. NCCN Guideline: Thyroid Carcinoma

Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer's prescribing information.
- Support for using Xgeva for the prevention of skeletal-related events in bone metastases from specific solid tumors is found in the National Comprehensive Cancer Network's guidelines for breast cancer, kidney cancer, non-small cell lung cancer, prostate cancer, and thyroid carcinoma.

- The NCCN Guideline for breast cancer supports use of Xgeva when used with calcium and vitamin D supplementation in addition to systemic therapy or endocrine therapy for bone metastasis in patients with expected survival of ≥3 months and adequate renal function in invasive and inflammatory breast cancers.
- The NCCN Guideline for kidney cancer supports use of Xgeva when used as a component of best supportive care for bony metastases.
- The NCCN Guideline for non-small cell lung cancer supports consideration of Xgeva in those with bone metastases.
- The NCCN Guideline for prostate cancer supports use of Xgeva for prevention of symptomatic skeletal-related events (SREs) in M1 castration-resistant prostate cancer (CRPC) if bone metastases present (preferred).
- The NCCN Guideline for thyroid carcinoma supports consideration of Xgeva for bone metastases in papillary, follicular, oncocytic, medullar, and anaplastic carcinomas.

- Support for using Xgeva in the treatment of giant cell tumor of the bone is also found in the National Comprehensive Cancer Network's guideline for bone cancer. The NCCN guideline for bone cancer supports use of Xgeva as:
  - Therapy as a single agent (preferred) or combined with serial embolization (preferred), and/or radiation therapy for resectable disease with unacceptable morbidity and/or unresectable axial lesions for patients with:
    - localized disease
    - metastases at presentation
    - disease recurrence
  - Preferred therapy as a single agent for:
    - unresectable metastatic disease at presentation
    - unresectable metastatic recurrence
    - considered prior to surgery for resectable local recurrence
- Support for using Xgeva for the prevention of skeletal-related events in multiple myeloma is found in the National Comprehensive Cancer Network's guideline for multiple myeloma. The NCCN Guideline for multiple myeloma supports use of Xgeva when used in combination with primary myeloma therapy (preferred agent in patients with renal insufficiency).
- Support for using biosimilars as step requirement is found in Noridian Health Care Solutions and supported by the FDA. Noridian will accept a biosimilar drug on the same criteria as the drug to which it is a biosimilar unless an article is published to the contrary. Per the FDA, a biosimilar is highly similar to and has no clinically meaningful difference from an existing FDA approved biologic reference drug.
- Support for using biosimilars in oncology can be found in The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) via the footnote on the reference product (an FDA-approved biosimilar is an appropriate substitute) and in the NCCN Drugs & Biologics Compendium® by the notation that a biosimilar agent may be an appropriate substitute for the reference product.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at https://www.cms.gov/Medicare-Coverage-Database/search.aspx

3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS. Available by subscription at http://www.lexi.com
5. Bomyntra (denosumab-bnht) Prescribing Information. Fresenius Kabi USA, LLC Lake Zurich, IL: 3/2025.
6. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
7. Xgeva (denosumab) Prescribing Information. Thousand Oaks, CA: Amgen Inc.; 6/2020.
8. Fuleihan G, Clines G, Hu M, et al. Treatment of Hypercalcemia of Malignancy in Adults: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism, 2023,108:507-528.
9. Osenvelt (denosumab-bmwo) Prescribing Information. Celltrion Inc. Jersey City, NJ: 2/2025.
10. National Comprehensive Cancer Network. Bone Cancer (Version 1.2025). Available at: www.nccn.org.
11. National Comprehensive Cancer Network. Breast Cancer (Version 4.2024). Available at: www.nccn.org.
12. National Comprehensive Cancer Network. Kidney Cancer (Version 1.2025). Available at: www.nccn.org.
13. National Comprehensive Cancer Network. Multiple Myeloma (Version 4.2024). Available at: www.nccn.org.
14. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer (Version 8.2024). Available at: www.nccn.org.
15. National Comprehensive Cancer Network. Prostate Cancer (Version 4.2024). Available at: www.nccn.org.
16. National Comprehensive Cancer Network. Systemic Mastocytosis (Version 3.2024). Available at: www.nccn.org.
17. National Comprehensive Cancer Network. Thyroid Carcinoma (Version 4.2024). Available at: www.nccn.org.
18. Wyost (denosumab-bbdz) Prescribing Information. Sandoz Inc., Princeton, NJ: 10/2024.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- Added Wyost, Osenvelt, and Bomyntra (FDA approved Xgeva biosimilars)
- All indications for Bomyntra, Osenvelt, Xgeva: ***Effective 1/1/2026 and after,*** will add pre-requisite therapy requirement with Wyost *(Rationale: cost effective therapeutic alternative available)*

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee

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