Drug Coverage Policy

Effective Date.....3/1/2026
Coverage Policy Number.....IP0332
Policy Title..... Xgeva

Bone Modifiers – Denosumab Products (Xgeva)

- Bilprevda® (denosumab-nxxp) subcutaneous injection –Shanghai Henlius Biotech/Organon)
- Bomyntra® (denosumab-bnht subcutaneous injection – Fresenius Kabi)
- Osenvelt® (denosumab-bmwo subcutaneous injection – Celltrion)
- Wyost® (denosumab-bbdz subcutaneous injection – Sandoz)
- Xbryk™ (denosumab-dssb subcutaneous injection – Samsung Bioepis)
- Xgeva® (denosumab subcutaneous injection – Amgen)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used

as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Denosumab products (Xgeva, biosimilars) are receptor activator of nuclear factor kappa-B ligand inhibitors indicated for the following uses:[1-6]

- **Giant cell tumor of bone**, treatment of adults and skeletally mature adolescents with disease that is unresectable or where surgical resection is likely to result in severe morbidity.
- **Hypercalcemia of malignancy**, treatment of, that is refractory to bisphosphonate therapy.
- **Skeletal-related events**, prevention, in patients with multiple myeloma and in those with bone metastases from solid tumors.

Another injectable formulation of denosumab subcutaneous injection is available, Prolia® (biosimilars) but it is not included in this policy.[7]

Guidelines

Several guidelines address denosumab products (Xgeva, biosimilars).

- **Cancer:** Various guidelines from the National Comprehensive Cancer Network (NCCN) [e.g., breast cancer, prostate cancer, lung cancer, multiple myeloma] recommend denosumab products (Xgeva, biosimilars), for the prevention of skeletal related adverse events.[8-11]
- **Hypercalcemia of Malignancy:** Guidelines from the Endocrine Society for the treatment of hypercalcemia of malignancy in adults (2023) have several recommendations.[12] In adults with hypercalcemia of malignancy, treatment with denosumab products (Xgeva, biosimilars) over an intravenous bisphosphonate is recommended.

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for benefit coverage of denosumab products (Xgeva, biosimilars). Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with denosumab products (Xgeva, biosimilars) as well as the monitoring required for adverse events and long-term efficacy, approval requires denosumab products (Xgeva, biosimilars) to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Note: Xbryk is not covered on the pharmacy and medical benefits for Employer Plans and Individual and Family Plans. Refer to the customer's benefit plan document for details of covered product(s).

Denosumab products (Xgeva, biosimilars) are considered medically necessary when ONE of the following is met (1, 2, 3, or 4)

FDA-Approved Indications

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1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
Note: Some examples of cancer in this clinical scenario include breast cancer, prostate cancer, and non-small cell lung cancer.

A) Patient is ≥ 18 years of age; AND

B) Patient has bone metastases; AND

C) Patient with prostate cancer must have castration-resistant prostate cancer; AND
Note: This includes patients who have progressed after treatment with hormonal therapy or after surgical castration (e.g., bilateral orchiectomy). Examples of hormonal therapies for prostate cancer include Lupron Depot (leuprolide for depot suspension), Eligard (leuprolide acetate for injectable suspension), Trelstar (triptorelin pamoate for injectable suspension), or Zoladex (goserelin implant).

D) Medication is prescribed by or in consultation with a hematologist or an oncologist.

E) Preferred product criteria are met for the product(s) as listed in the below table(s)

Dosing. Approve 120 mg administered as a subcutaneous (SC) injection up to once every 4 weeks.

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2. Giant Cell Tumor of Bone. Approve for 1 year. if the patients meets the following (A):

A) Preferred product criteria are met for the product(s) as listed in the below table(s)

Dosing. Approve 120 mg subcutaneous (SC) up to once every 4 weeks with loading doses on Day 8 and Day 15 of Month 1.

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3. Hypercalcemia of Malignancy. Approve for 2 months if the patient meets BOTH of the following (A, B, and C):

A) Patient has a current malignancy; AND

B) Patient has an albumin-corrected calcium (cCa) ≥ 11.5 mg/dL.

C) Preferred product criteria are met for the product(s) as listed in the below table(s)

Dosing. Approve 120 mg subcutaneous (SC) up to once every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy.

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4. Multiple Myeloma – Prevention of Skeletal-Related Events. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) The medication is prescribed by or in consultation with a hematologist or an oncologist.

C) Preferred product criteria are met for the product(s) as listed in the below table(s)

Dosing. Approve 120 mg administered as a subcutaneous (SC) injection up to once every 4 weeks.

Employer Plans:

Product	Criteria
Bilprevda (denosumab-nxxp) subcutaneous injection)	Patient meets ONE of the following (1, 2, 3 or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **BOTH** of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets **ONE** of the following (i, ii, iii, or iv): **i.** Patient tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars); OR **iv.** Patient has prostate cancer with bone metastases. **2. Giant Cell Tumor of Bone.** Patent meets the above medical necessity criteria. **3. Hypercalcemia of Malignancy.** Patent meets the above medical necessity criteria. **4. Multiple Myeloma – Prevention of Skeletal-Related Events.** Patient meets BOTH of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets **ONE** of the following (i, ii, or iii): **i.** Patient has tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars).
Bomyntra (denosumab-bnht subcutaneous injection)	Patient meets BOTH of the following (A and B): **A.** Patient meets ONE of the following (1, 2, 3, or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **BOTH** of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets ONE of the following (i, ii, iii, or iv): **i.** Patient tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars); OR **iv.** Patient has prostate cancer with bone metastases. **2. Giant Cell Tumor of Bone.** Patent meets the above medical necessity criteria. **3. Hypercalcemia of Malignancy.** Patent meets the above medical necessity criteria. **4. Multiple Myeloma – Prevention of Skeletal-Related Events.** Patient meets BOTH of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets ONE of the following (i, ii, or iii): **i.** Patient has tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars). **B.** Patient meets BOTH of the following (1 and 2):

Product	Criteria
	1. Patient has tried ALL of the following: Bilprevda, Wyost, and Xgeva; AND **2.** Patient cannot continue to use each of the formulary alternative(s) due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.
Osenvelt (denosumab-bmwo subcutaneous injection)	Patient meets BOTH of the following (A and B): **A.** Patient meets ONE of the following (1, 2, 3, or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **BOTH** of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets ONE of the following (i, ii, iii, or iv): **i.** Patient tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars); OR **iv.** Patient has prostate cancer with bone metastases. **2. Giant Cell Tumor of Bone.** Patient meets the above medical necessity criteria. **3. Hypercalcemia of Malignancy.** Patient meets the above medical necessity criteria. **4. Multiple Myeloma – Prevention of Skeletal-Related Events.** Patient meets BOTH of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets ONE of the following (i, ii, or iii): **i.** Patient has tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars). **B.** Patient meets BOTH of the following (1 and 2): **1.** Patient has tried ALL of the following: Bilprevda, Wyost, and Xgeva; AND **2.** Patient cannot continue to use each of the formulary alternative(s) due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.
Wyost (denosumab-bbdz subcutaneous injection)	Patient meets **ONE** of the following (1, 2, 3, or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **BOTH** of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets **ONE** of the following (i, ii, iii, or iv): **i.** Patient tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars); OR

Product	Criteria
	iv. Patient has prostate cancer with bone metastases. **2. Giant Cell Tumor of Bone.** Patient meets the above medical necessity criteria. **3. Hypercalcemia of Malignancy.** Patient meets the above medical necessity criteria. **4. Multiple Myeloma – Prevention of Skeletal-Related Events.** Patient meets BOTH of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets **ONE** of the following (i, ii, or iii): **i.** Patient has tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars).
Xbryk (denosumab-dssb subcutaneous injection)	Xbryk is not approved. A request for the Preferred Products, Bilprevda, Wyost, or Xgeva, may be reviewed.
Xgeva (denosumab subcutaneous injection)	Patient meets ONE of the following (1, 2, 3, or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **BOTH** of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets **ONE** of the following (i, ii, iii, or iv): **i.** Patient tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars); OR **iv.** Patient has prostate cancer with bone metastases. **2. Giant Cell Tumor of Bone.** Patient meets the above medical necessity criteria. **3. Hypercalcemia of Malignancy.** Patient meets the above medical necessity criteria. **4. Multiple Myeloma – Prevention of Skeletal-Related Events.** Patient meets BOTH of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets **ONE** of the following (i, ii, or iii): **i.** Patient has tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars).

Individual and Family Plans:

Product	Criteria
Bilprevda (denosumab-nxxp) subcutaneous injection)	Patient meets ONE of the following (1, 2, 3 or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **BOTH** of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets **ONE** of the following (i, ii, iii, or iv): **i.** Patient tried zoledronic acid injection (Zometa); OR

Product	Criteria
	ii. Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars); OR **iv.** Patient has prostate cancer with bone metastases. **2. Giant Cell Tumor of Bone.** Patent meets the above medical necessity criteria. **3. Hypercalcemia of Malignancy.** Patent meets the above medical necessity criteria. **4. Multiple Myeloma – Prevention of Skeletal-Related Events.** Patient meets BOTH of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets **ONE** of the following (i, ii, or iii): **i.** Patient has tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars).
Bomyntra (denosumab-bnht subcutaneous injection)	Patient meets BOTH of the following (A and B): **A.** Patient meets ONE of the following (1, 2, 3, or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **BOTH** of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets ONE of the following (i, ii, iii, or iv): **i.** Patient tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars); OR **iv.** Patient has prostate cancer with bone metastases. **2. Giant Cell Tumor of Bone.** Patient meets the above medical necessity criteria. **3. Hypercalcemia of Malignancy.** Patient meets the above medical necessity criteria. **4. Multiple Myeloma – Prevention of Skeletal-Related Events.** Patient meets BOTH of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets ONE of the following (i, ii, or iii): **i.** Patient has tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars). **B.** Patient meets BOTH of the following (1 and 2): **1.** Patient has tried ALL of the following: Bilprevda, Wyost, and Xgeva; AND **2.** Patient cannot continue to use each of the formulary alternative(s) due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.

Product	Criteria
Osenvelt (denosumab-bmwo subcutaneous injection)	Patient meets BOTH of the following (A and B): **A.** Patient meets ONE of the following (1, 2, 3, or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **BOTH** of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets **ONE** of the following (i, ii, iii, or iv): **i.** Patient tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars); OR **iv.** Patient has prostate cancer with bone metastases. **2. Giant Cell Tumor of Bone.** Patient meets the above medical necessity criteria. **3. Hypercalcemia of Malignancy.** Patient meets the above medical necessity criteria. **4. Multiple Myeloma – Prevention of Skeletal-Related Events.** Patient meets BOTH of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets **ONE** of the following (i, ii, or iii): **i.** Patient has tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars). **B.** Patient meets BOTH of the following (1 and 2): **1.** Patient has tried ALL of the following: Bilprevda, Wyost, and Xgeva; AND **2.** Patient cannot continue to use each of the formulary alternative(s) due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.
Wyost (denosumab-bbdz subcutaneous injection)	Patient meets ONE of the following (1, 2, 3, or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **BOTH** of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets ONE of the following (i, ii, iii, or iv): **i.** Patient tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars); OR **iv.** Patient has prostate cancer with bone metastases. **2. Giant Cell Tumor of Bone.** Patient meets the above medical necessity criteria. **3. Hypercalcemia of Malignancy.** Patient meets the above medical necessity criteria. **4. Multiple Myeloma – Prevention of Skeletal-Related Events.** Patient meets BOTH of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND

Product	Criteria
	B) Patient meets ONE of the following (i, ii, or iii): **i.** Patient has tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars).
Xbryk (denosumab-dssb subcutaneous injection)	Xbryk is not approved. A request for the Preferred Products, Bilprevda, Wyost, or Xgeva, may be reviewed.
Xgeva (denosumab subcutaneous injection)	Patient meets ONE of the following (1, 2, 3, or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **BOTH** of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets ONE of the following (i, ii, iii, or iv): **i.** Patient has tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars); OR **iv.** Patient has prostate cancer with bone metastases. **2. Giant Cell Tumor of Bone.** Patient meets the above medical necessity criteria. **3. Hypercalcemia of Malignancy.** Patient meets the above medical necessity criteria. **4. Multiple Myeloma – Prevention of Skeletal-Related Events.** Patient meets BOTH of the following (A and B): **A)** Patient meets the above medical necessity criteria; AND **B)** Patient meets ONE of the following (i, ii, or iii): **i.** Patient has tried zoledronic acid injection (Zometa); OR **ii.** Patient has renal impairment (creatinine clearance < 30 mL/min); OR **iii.** Patient is currently taking or has a previous history of using denosumab products (Xgeva, biosimilars).

Conditions Not Covered

Denosumab products (Xgeva, biosimilars) for any other use is considered not medically necessary. Criteria will be updated as newly published data are available.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J0897	Injection, denosumab, 1 mg
J3490	Unclassified drugs
J3590	Unclassified biologic
C9399	Unclassified drugs or biologicals
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
Q5159	Injection, denosumab-dssb (Ospomyv/Xbryk), biosimilar, 1 mg

References

1. Xgeva® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; June 2020.
2. Wyost® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; March 2024.
3. Osenvelt® subcutaneous injection [prescribing information]. Jersey City, NJ: Celltrion; February 2025.
4. Bomyntra® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; March 2025.
5. Bilprevda® subcutaneous injection [prescribing information]. Jersey City, NJ: Shanghai Henlius Biotech/Organon; August 2025.
6. Xbryk™ subcutaneous injection [prescribing information]. Incheon, Republic of Korea: Samsung Bioepis; February 2025.
7. Prolia® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; March 2024.
8. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – December 4, 2024). © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 14, 2025.
9. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – March 5, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 14, 2025.
10. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 1.2025 – September 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 14, 2025.
11. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 14, 2025.
12. Ghada El-Hajj Fuleihan, Clines GA, Hu MI, et al. Treatment of hypercalcemia of malignancy in adults: an Endocrine Society Clinical Practice guideline. *J Clin Endocrinol Metab*. 2023;108(3):507-528.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Updated the policy title. **Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events:** Relocated zoledronic acid requirement and the exceptions to a preferred product table and added	06/15/2024

	an additional exception for "Patient has renal impairment (creatinine clearance < 30 mL/min)"; Updated statement "Is currently receiving denosumab (Xgeva) and has demonstrated a beneficial clinical response" to now be "Patient has a previous history of using Xgeva" **Giant Cell Tumor of Bone:** Removed specialist prescriber requirement **Hypercalcemia of Malignancy:** Updated authorization approval duration to 2 months, was previously 12 months; Removed specialist prescriber requirement **Multiple Myeloma** – **Prevention of Skeletal-Related Events:** Relocated zoledronic acid requirement and the exceptions to a preferred product table and added an additional exception for "Patient has renal impairment (creatinine clearance < 30 mL/min)"; Updated statement "Is currently receiving denosumab (Xgeva) and has demonstrated a beneficial clinical response" to now be "Patient has a previous history of using Xgeva".	
Annual Revision	No criteria changes.	06/15/2025
Selected Revision	Osenvelt and Wyost was added to the policy with the same criteria as Xgeva. The Policy name was changed from "Bone Modifiers – Xgeva" to "Bone Modifiers – Denosumab Products (Xgeva)." **Preferred Product Criteria Table for Employer and Individual and Family plans.** **Added** step requirement criteria for Osenvelt and Wyost **Updated** Xgeva criteria from "failure, contraindication or intolerance" to "tried" zoledronic acid injection (Zometa). **Coding Information:** Added HCPCS: Q5136, C9399, J3490, J3590	08/15/2025
Selected Revision	Bomyntra was added to the policy with the same criteria as the other denosumab (Xgeva, biosimilars) products. **Updated** the policy statement. **Preferred Product Criteria Table for Employer and Individual and Family plans.** **Added** preferred product requirements for Bomyntra. **Updated** preferred product requirements for Osenvelt. **Updated** preferred product requirements for Wyost and Xgeva. **Coding Information:** **Added** HCPCS codes: Q5157, Q5158 **Removed** HCPCS codes: C9399, J3490, J3590	12/15/2025

Selected Revision	**Added** Bilprevda to the policy with the same criteria as the other denosumab (Xgeva, biosimilars) products. **Added** Xbryk to the policy with a "Note" stating that Xbryk is not covered on the pharmacy and medical benefits for Employer Plans and Individual and Family Plans. Refer to the customer's benefit plan document for details of covered product(s). **Preferred Product Table:** **Added** Bilprevda as a step through product for both Bomyntra and Osenvelt, for both Employer Plans and Individual and Family Plans. **Coding information:** **Added HCPCS Codes:** J3490 J3590 C9399 Q5159	3/1/2026

The policy effective date is in force until updated or retired.