Drug Coverage Policy

Effective Date……7/1/2026
Coverage Policy Number……PSM034
Policy Title……Denosumab Products (Xgeva) Preferred Specialty Management Policy

Bone Modifiers – Denosumab Products (Xgeva) Preferred Specialty Management Policy

- Aukelso™ (denosumab-kyqq subcutaneous injection – Biocon)
- Bilprevda® (denosumab-nxxp subcutaneous injection – Organon)
- Bomyntra® (denosumab-bnht subcutaneous injection – Fresenius Kabi)
- Osenvelt® (denosuamb-bmwo subcutaneous injection – Celltrion)
- Wyost® (denosumab-bbdz subcutaneous injection – Sandoz)
- Xbryk™ (denosumab-dssb subcutaneous injection – Samsung Bioepis)
- Xgeva® (denosumab subcutaneous injection – Amgen)
- Xtrenbo™ (denosumab-qbde subcutaneous injection – Hikma)

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 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 disease that is refractory to bisphosphonate therapy.
- **Skeletal-related events**, prevention in patients with multiple myeloma and in those with bone metastases from solid tumors.

Aukelso, Bilprevda, Bomyntra, Osenvelt, Wyost, and Xtrenbo were approved as biosimilars to Xgeva, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Xgeva. However, minor differences in clinically inactive components are allowed.

Coverage Policy

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all products (Preferred and Non-Preferred), the patient is required to meet the standard *Bone Modifiers – Denosumab Products (Xgeva) Prior Authorization Policy* criteria. The program also directs the patient to try all Preferred Products prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for the duration noted in the standard *Bone Modifiers – Denosumab Products (Xgeva) Prior Authorization Policy*. If the patient meets the standard *Bone Modifiers - Denosumab Products (Xgeva) Prior Authorization Policy* criteria but has not tried the Preferred Product, approval for the Preferred Product(s) will be authorized.

Documentation: Documentation is required for previous use of the preferred drug(s) as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.

Preferred Products: Bilprevda, Wyost
Non-Preferred Products: Aukelso, Bomyntra, Osenvelt, Xbryk, Xgeva, Xtrenbo

Bone Modifiers – Denosumab Products (Xgeva) non-preferred products are considered medically necessary when the following non-preferred product exception criteria are met. Any other exception is considered not medically necessary.

Non-Preferred Product Exception Criteria for Employer Plans and Individual and Family Plans:

Product	Criteria
Bilprevda, Wyost	Approve if the patient meets **ONE** of the following (1, 2, 3, or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **ALL** of the following (A and B): **A)** Patient meets the standard *Bone Modifiers – Denosumab Products (Xgeva) Prior Authorization Policy* 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 standard *Bone Modifiers – Denosumab Products (Xgeva) Prior Authorization Policy* criteria. **3. Hypercalcemia of Malignancy.** Patient meets the standard *Bone Modifiers – Denosumab Products (Xgeva) Prior Authorization Policy* criteria. **4. Multiple Myeloma – Prevention of Skeletal Related events.** Patient meets **ALL** of the following (A and B): **A)** Patient meets the standard *Bone Modifiers – Denosumab Products (Xgeva) Prior Authorization Policy* 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)
Aukelso, Bomyntra, Osenvelt, Xgeva, Xtrenbo	Approve if the patient meets **ONE** of the following (1, 2, 3, or 4): **1. Bone Metastases from Solid Tumors – Prevention of Skeletal-Related Events.** Patient meets **ALL** of the following (A, B, C, and D): **A)** Patient meets the standard *Bone Modifiers – Denosumab Products (Xgeva) Prior Authorization Policy* 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. **C)** Patient has tried BOTH of the following: Bilprevda and Wyost **[documentation required]**; AND **D)** Patient cannot continue to use the Preferred product due to a formulation difference in the inactive ingredient(s) [e.g., difference in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in

Product	Criteria
	a significant allergy or serious adverse reaction **[documentation required]**. **2. Giant Cell Tumor of Bone.** Patient meets **ALL** of the following (A, B, and C): **A)** Patient meets the standard *Bone Modifiers – Denosumab Products (Xgeva) Prior Authorization Policy* criteria; AND **B)** Patient has tried BOTH of the following: Bilprevda and Wyost **[documentation required]**; AND **C)** Patient cannot continue to use the Preferred product due to a formulation difference in the inactive ingredient(s) [e.g., difference in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **3. Hypercalcemia of Malignancy.** Patient meets **ALL** of the following (A, B, and C): **A)** Patient meets the standard *Bone Modifiers – Denosumab Products (Xgeva) Prior Authorization Policy* criteria; AND **B)** Patient has tried BOTH of the following: Bilprevda and Wyost **[documentation required]**; AND **C)** Patient cannot continue to use the Preferred product due to a formulation difference in the inactive ingredient(s) [e.g., difference in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **4. Multiple Myeloma – Prevention of Skeletal Related events.** Patient meets **ALL** of the following (A, B, C, and D): **A)** Patient meets the standard *Bone Modifiers – Denosumab Products (Xgeva) Prior Authorization Policy* 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 **C)** Patient has tried BOTH of the following: Bilprevda and Wyost **[documentation required]**; AND **D)** Patient cannot continue to use the Preferred product due to a formulation difference in the inactive ingredient(s) [e.g., difference in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**.
Xbryk	Xbryk is not approved. A request for the Preferred Products, Bilprevda or Wyost may be reviewed.

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: Organon; September 2025.
6. Xbryk™ subcutaneous injection [prescribing information]. Incheon, Republic of Korea: Samsung Bioepis; February 2025.
7. Xtrenbo™ subcutaneous injection [prescribing information]. Cherry Hill, NJ: Hikma, September 2025.
8. Aukelso™ subcutaneous injection [prescribing information]. Cambridge, MA: Biocon; September 2025.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy.	4/30/2026	7/1/2026

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