EXPRESS SCRIPTS®

MED RX POLICY

POLICY: Bone Modifiers – Denosumab Products (Xgeva) Med Rx Policy

- Bilprevda® (denosumab-nxxp) subcutaneous injection – Organon)
- Bomyntra® (denosumab-bnht subcutaneous injection – Fresenius Kabi)
- Osenvelt® (denosumab-bmwo subcutaneous injection – Celltrion)
- Wyost® (denosumab-bbdz subcutaneous injection – Sandoz)
- Xgeva® (denosumab subcutaneous injection – Amgen)
- Xtrenbo™ (denosumab-qbde subcutaneous injection – Hikma)

REVIEW DATE: 09/03/2025; selected revision 10/15/2025, 01/21/2026 and 02/11/2026

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.

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.

POLICY STATEMENT

This Med Rx program has been developed to encourage the use of Preferred Products. For all Non-Preferred Products, the patient is required to meet the standard *Bone Modifiers – Denosumab Products (Xgeva) Utilization Management Medical Policy* criteria. The program also directs the patient to try at least two 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) Utilization Management Medical Policy*.

Automation: None

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

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Bilprevda, Bomyntra, Xtrenbo	**1.** Approve if the patient meets ALL of the following (A, B and C): **A)** Patient meets the standard *Bone Modifiers – Denosumab Products (Xgeva) Utilization Management Medical Policy* criteria; AND **B)** Patient has tried at least TWO of the following: Osenvelt, Wyost, or Xgeva; AND **C)** Patient cannot continue to use the Preferred products 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.

REFERENCES

1. Xgeva® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; May 2025.
2. Bomyntra® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; March 2025.
3. Osenvelt® subcutaneous injection [prescribing information]. Jersey City, NJ: Celltrion; February 2025.
4. Wyost® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; March 2024.
5. Bilprevda® subcutaneous injection [prescribing information]. Jersey City, NJ: Organon; September 2025.
6. Xtrenbo™ subcutaneous injection [prescribing information]. Cherry Hill, NJ: Hikma, September 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Effective 01/01/2026.	09/03/2025
Selected Revision	**Effective 01/01/2026.** Bilprevda was added to the policy as a Non-Preferred product. The same exception criteria apply as the other Non-Preferred products.	10/15/2025
Selected Revision	Xtrenbo was added to the policy as a Non-Preferred product. The same exception criteria apply as the other Non-Preferred products. **Effective 07/01/2026.** Bilprevda and Bomyntra were moved to Preferred. Osenvelt and Xgeva were moved to Non-Preferred. The exception criteria were updated to reflect the new Preferreds.	01/21/2026
Selected Revision	Osenvelt and Xgeva were moved to Preferred. Bilprevda and Bomyntra were moved to Non-Preferred. The exception criteria were updated to reflect the new Preferreds.	02/11/2026