POLICY Document for XTRENBO

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
ONCOLOGY DENOSUMAB PRODUCTS

PREFERRED PRODUCTS: BILPREVDA, OSENVELT

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the denosumab products used to treat oncology indications specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Denosumab Oncology Products

	Product(s)
Preferred*	• **Bilprevda** (denosumab-nxxp) • **Osenvelt** (denosumab-bmwo)
Targeted	• **Aukelso** (denosumab-kyqq) • **Bomyntra** (denosumab-bnht) • **Wyost** (denosumab-bbdz) • **Xbryk** (denosumab-dssb) • **Xgeva** (denosumab)

	• **Xtrenbo** (denosumab-qbde)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

a. Coverage for the targeted product is provided when member has a documented inadequate response, contraindication, or intolerable adverse event to both preferred products and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

Section 2: Clinical Criteria

Specialty Guideline Management
Xgeva and Biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Xgeva	denosumab
Aukelso	denosumab-kyqq
Bilprevda	denosumab-nxxp
Bomyntra	denosumab-bnht
Jubereq	denosumab-desu
Osenvelt	denosumab-bmwo
Oziltus	denosumab-mobz
Wyost	denosumab-bbdz
Xbryk	denosumab-dssb
Xtrenbo	denosumab-qbde

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1-10]

- 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

Compendial Uses[11]

- Second-line therapy for osteopenia/osteoporosis in patients with systemic mastocytosis
- Thyroid cancer as palliative care for bone metastases

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Multiple Myeloma[1-11]

Authorization of 12 months may be granted for prevention of skeletal-related events in members with multiple myeloma.

Bone Metastases From a Solid Tumor[1-11]

Authorization of 12 months may be granted for either of the following:

- For prevention of skeletal-related events in members with bone metastases from a solid tumor (e.g., breast cancer, non-small cell lung cancer, thyroid carcinoma, kidney cancer, prostate cancer)
- As palliative care for bone metastases from thyroid carcinoma

Giant Cell Tumor of Bone[1-11]

Authorization of 12 months may be granted for treatment of giant cell tumor of bone.

Hypercalcemia of Malignancy[1-10,12-13]

Authorization of 2 months may be granted for treatment of hypercalcemia of malignancy that is refractory to intravenous (IV) bisphosphonate therapy OR there is a clinical reason to avoid IV bisphosphonate therapy (e.g., history of intolerance or hypersensitivity to an IV bisphosphonate).

Systemic Mastocytosis[11]

Authorization of 12 months may be granted for second-line therapy for osteopenia or osteoporosis in members with systemic mastocytosis that have not responded to therapy with bisphosphonates or who are not candidates for bisphosphonates because of renal insufficiency.

Continuation of Therapy

Hypercalcemia of Malignancy

Authorization of 2 months may be granted for continued treatment in members requesting reauthorization for hypercalcemia of malignancy who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

REFERENCES:

SECTION 1

1. Aukelso [package insert]. Cambridge, MA: Biocon Biologics Inc.; September 2025.
2. Bilprevda [package insert]. Jersey City, NJ: Organon LLC; August 2025.
3. Bomyntra [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2025.
4. Osenvelt [package insert]. Jersey City, NJ: Celltrion USA, Inc.; September 2025.
5. Wyost [package insert]. Princeton, NJ: Sandoz Inc.; October 2024.
6. Xbryk [package insert]. Incheon, South Korea: Samsung Bioepis; February 2025.
7. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2025.
8. Xtrenbo [package insert]. Cherry Hill, NJ: Hikma Pharmaceuticals USA Inc.; September 2025.

SECTION 2

1. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2025.
2. Aukelso [package insert]. Cambridge, MA: Biocon Biologics Inc.; September 2025.
3. Bilprevda [package insert]. Jersey City, NJ: Organon LLC; August 2025.
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5. Jubereq [package insert]. Raleigh, NC; Accord BioPharma Inc.; October 2025.
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11. The NCCN Drugs & Biologics Compendium™ © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed December 8, 2025.
12. Hu M, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. J Clin Endocrinol Metab. 2014;99(9):3144-3152.
13. El-Hajj Fuleihan G, 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.