POLICY Document for AUKELSO

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 3: Oncology Clinical Policy
- Policy information specific to regimen review per NCCN Guidelines.

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

CVS/caremark

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.

Section 3: Oncology Clinical Policy

PURPOSE

The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

SCOPE

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their medical and/or pharmacy prior authorization solution.

Program Description

The National Comprehensive Care Network® (NCCN®) is a not-for profit alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness and efficiency of cancer care so patients can live better lives. It is comprised of oncology experts who convene regularly to establish the best treatments for patients.[1]

NCCN develops resources to support stakeholders in the health care delivery system including the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

The Guidelines offer broad, high-level, evidence-based recommendations for cancer management. The Compendium extracts the drug and biologic recommendations from the Guidelines detailing their use and level of evidence category. The Templates convert the drug regimens detailed in the Guidelines and Compendium into practical, standardized order sets for safe, clinical use. [2,3]

NCCN Categories of Evidence and Consensus[4]

- **Category 1:** Based upon high-level evidence, there is uniform (defined as ≥85% panel support) NCCN consensus that the intervention is appropriate.
- **Category 2A:** Based upon lower-level evidence, there is uniform (≥85% panel support) NCCN consensus that the intervention is appropriate.
- **Category 2B:** Based upon lower-level evidence, there is NCCN consensus (50% to <85% panel support) that the intervention is appropriate.
- **Category 3:** Based upon any level of evidence, there is major NCCN disagreement (less than 50% panel support, or at least three institutions opposing the recommendation) that the intervention is appropriate.

Policy for Regimen Prior Authorization

Regimen prior authorization allows providers to submit a single request for all oncology drugs or biologics within an NCCN Template that require prior authorization. Regimen requests must be initiated through the provider portal. If submitted via phone or fax, each drug or biologic must be requested individually using drug-specific criteria.

Coverage is provided for a regimen request when all the following criteria are met. If all are not met, further review may be required:

1. The request is initiated through the provider portal.
2. The member is eligible for regimen review.
3. The request is for an oncology drug or biologic.
4. The requested regimen and indication align with an NCCN recommendation with a level of evidence category 1 or 2A.
5. The NCCN template is accepted by the provider without modification.
6. The indication is for a cancer type currently eligible for regimen review.
6. The indication is for a cancer type currently eligible for regimen review.
    1. Ampullary Adenocarcinoma
    2. Anal Carcinoma
    3. Appendiceal Neoplasms and Cancers
    4. Basal Cell Skin Cancer
    5. B-Cell Lymphomas
    6. Biliary Tract Cancers
    7. Bladder Cancer
    8. Bone Cancer
    9. Breast Cancer
    10. Castleman Disease
    11. Central Nervous System Cancers

12. Cervical Cancer
13. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
14. Chronic Myeloid leukemia
15. Colon Cancer
16. Cutaneous Lymphomas
17. Dermatofibrosarcoma Protuberans
18. Esophageal Cancer
19. Gastric Cancer
20. Gastrointestinal Stromal Tumors
21. Gestational Trophoblastic Neoplasms
22. Hairy Cell Leukemia
23. Head and Neck Cancers
24. Hepatocellular Carcinoma
25. Histiocytic Neoplasms
26. Hodgkin Lymphoma
27. Kaposi Sarcoma
28. Kidney Cancer
29. Melanoma: Cutaneous
30. Melanoma: Uveal
31. Merkel Cell Carcinoma
32. Mesothelioma: Peritoneal
33. Mesothelioma: Pleural
34. Multiple Myeloma
35. Myelodysplastic Syndromes
36. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
37. Myeloproliferative Neoplasms
38. Neuroendocrine and Adrenal Tumors
39. Non-Small Cell Lung Cancer
40. Occult Primary
41. Ovarian Cancer
42. Pancreatic Cancer
43. Penile Cancer
44. Prostate Cancer
45. Rectal Cancer
46. Small Bowl Adenocarcinoma
47. Small Cell Lung Cancer
48. Soft Tissue Sarcoma
49. Squamous Cell Skin Cancer
50. Systemic Light Chain Amyloidosis
51. Systemic Mastocytosis
52. T-Cell Lymphomas
53. Testicular Cancer
54. Thymomas and Thymic Carcinomas
55. Thyroid Carcinoma
56. Uterine Neoplasms

57. Vaginal Cancer
58. Vulvar Cancer
59. Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
60. Wilms Tumor (Nephroblastoma)

Supportive Care: Myeloid Growth Factor Therapy

Granulocyte colony stimulating factors (G-CSFs) are recommended for primary prophylaxis based on the febrile neutropenia (FN) risk of the chemotherapy regimen. The level of FN risk varies by NCCN Template and is indicated at the top of each template. Regimens classified as high or intermediate risk of FN may include a G-CSF as part of the prior authorization

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and evidence-based practice guidelines.

Duration of Approval

Authorizations may be granted for 12 months or as medically necessary, based on the member's condition and provider's clinical assessment.

Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. If no specific template exists for the intended maintenance therapy, the selected template can be modified to include only the appropriate maintenance agents. The modified regimen request will be submitted for further review.

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.
4. Bomyntra [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2025.
5. Jubereq [package insert]. Raleigh, NC; Accord BioPharma Inc.; October 2025.
6. Osenvelt [package insert]. Jersey City, NJ: Celltrion USA, Inc.; September 2025..
7. Oziltus [package insert]. Piscataway, NJ: Amneal Pharmaceuticals LLC; October 2025.

8. Wyost [package insert]. Princeton, NJ: Sandoz Inc.; October 2024.
9. Xbryk [package insert]. Incheon, South Korea: Samsung Bioepis; February 2025.
10. Xtrenbo [package insert]. Cherry Hill, NJ: Hikma Pharmaceuticals USA Inc.; September 2025.
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.

SECTION 3

1. National Comprehensive Cancer Network. *About NCCN*. Available at: https://www.nccn.org/home/about. Accessed September 10, 2025.
2. National Comprehensive Cancer Network. *NCCN Guidelines*. Available at: https://www.nccn.org/guidelines/category_1. Accessed September 10, 2025. *(Note: An account may be required.)*
3. National Comprehensive Cancer Network. *NCCN Drugs and Biologics Compendium*. Available at: https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia. Accessed September 10, 2025. *(Note: A subscription may be required.)*
4. National Comprehensive Cancer Network. *NCCN Categories of Evidence and Consensus*. Available at: https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines. Accessed September 10, 2025.