DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Bone Modifiers – Denosumab Products (Xgeva) Drug Quantity Management Policy – Per Rx

- Xgeva® (denosumab subcutaneous injection – Amgen)
- Aukelso™ (denosumab-kyqq subcutaneous injection – Biocon)
- 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)
- Xtrenbo™ (denosumab-qbde subcutaneous injection – Hikma)

REVIEW DATE: 12/03/2025; selected revisions 03/11/2026 and 03/25/2026

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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Denosumab products (Xgeva, biosimilars) are receptor activator of nuclear factor kappa-B ligand inhibitors indicated for the following uses[1-7]:

- **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 of, in patients with multiple myeloma and in those with bone metastases from solid tumors.

Another injectable formulation of denosumab is available (Prolia®, biosimilars), but it is not included in this policy.[8]

Dosing

Denosumab products (Xgeva, biosimilars) should be administered by a healthcare professional.[1-7]

- **Giant Cell Tumor of Bone and Hypercalcemia of Malignancy:** 120 mg given by subcutaneous (SC) injection once every 4 weeks (Q4W) with additional doses of 120 mg on Days 8 and 15 of the first month of therapy.
- **Skeletal-related events:** 120 mg SC Q4W.

Availability

Xgeva, Aukelso, Bilprevda, Bomyntra, Osenvelt, Wyost, and Xtrenbo are available as 120 mg/1.7 mL single-dose vials.[1-7] Bomyntra is also available as a 120 mg/1.7 mL prefilled syringe.[3]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of denosumab products (Xgeva, biosimilars). If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. "One-time" approvals are provided for 30 days in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Xgeva® (denosumab SC injection) Aukelso™ (denosumab-kyqq SC injection) Bilprevda® (denosumab-nxxp SC injection) Bomyntra® (denosumab-bnht SC injection) Osenvelt® (denosumab-bmwo SC injection) Wyost® (denosumab-bbdz SC injection)	120 mg/1.7 mL vials 120 mg/1.7 mL prefilled syringes (Bomyntra only)	1.7 mL (1 vial or syringe)	5.1 mL (3 vials or syringes)

Xtrenbo™ (denosumab-qbde SC injection)			

SC – Subcutaneous.

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

1. If the patient has giant cell tumor of bone and is initiating therapy, approve a one-time override for 5.1 mL (3 vials or syringes) at retail or home delivery.

2. If the patient has hypercalcemia of malignancy and is initiating therapy or is repeating treatment (up to six times per year), approve a one-time override 5.1 mL (3 vials or syringes) at retail or home delivery.

REFERENCES

1. Xgeva® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; June 2025.
2. Bilprevda® subcutaneous injection [prescribing information]. Jersey City, NJ: Shanghai Henlius Biotech/Organon; August 2025.
3. Bomyntra® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; March 2025.
4. Osenvelt® subcutaneous injection [prescribing information]. Jersey City, NJ: Celltrion; February 2025.
5. Wyost® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; October 2025.
6. Xtrenbo™ subcutaneous injection [prescribing information]. Cherry Hill, NJ: Hikma; September 2025.
7. Aukelso™ subcutaneous injection [prescribing information]. Cambridge, MA: Biocon; September 2025.
   Prolia® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; September 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	01/23/2023
Annual Revision	No criteria changes.	02/07/2024
Annual Revision	Policy statement was updated to note that "one-time" approvals are provided for 30 days in duration. Updated criteria to remove "the requested quantity, not to exceed."	02/10/2025
Early Annual Revision	Policy name was updated to "Bone Modifiers – Denosumab Products (Xgeva) DQM Policy – Per Rx"; previously the policy was named "Bone Modifiers – Xgeva DQM Policy – Per Rx". **Bilprevda 120 mg/1.7 mL vials:** Bilprevda was added to the policy. The same quantity limits and overrides apply to Bilprevda as have previously applied to other denosumab products (Xgeva). **Bomyntra 120 mg/1.7 mL vials and prefilled syringes:** Bomyntra was added to the policy. The same quantity limits and overrides apply to Bomyntra as have previously applied to other denosumab products (Xgeva). **Osenvelt 120 mg/1.7 mL vials:** Osenvelt was added to the policy. The same quantity limits and overrides apply to Osenvelt as have previously applied to other denosumab products (Xgeva). **Wyost 120 mg/1.7 mL vials:** Wyost was added to the policy. The same quantity limits and overrides apply to Wyost as have previously applied to other denosumab products (Xgeva).	12/03/2025
Selected Revision	**Xtrenbo 120 mg/1.7 mL vials:** Xtrenbo was added to the policy. The same quantity limits and overrides apply to Xtrenbo as have previously applied to other denosumab products (Xgeva).	03/11/2026
Selected Revision	**Aukelso 120 mg/1.7 mL vials:** Aukelso was added to the policy. The same quantity limits and overrides apply to Aukelso as have previously applied to other denosumab products (Xgeva).	03/25/2026