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Medication Policy Manual

Policy No: dru393

Topic: Denosumab Products for Malignancy-Related Indications

- Aukelso, denosumab-kyqq
- Bilprevda, denosumab-nxxp
- Bomyntra, denosumab-bnht
- Jubereq, denosumab-desu
- Osenvelt, denosumab-bmwo
- Oziltus, denosumab-mobz
- Wyost, denosumab-bbdz
- Xgeva, denosumab
- Xtrenbo, denosumab-qbde

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IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Denosumab is a medication used to prevent skeletal complications of bone metastases from solid tumor cancers and multiple myeloma. In addition, it is also used for the treatment of giant cell tumor of the bone and hypercalcemia of malignancy. It is a monoclonal antibody that targets the receptor activator of nuclear factor kappa B ligand (RANKL). Denosumab prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts, their precursors, and osteoclast-like giant cells.

PLEASE NOTE: Denosumab, also marketed for the treatment of osteoporosis (bone loss), has a separate medication policy (Denosumab Products for Osteoporosis dru223).

Policy/Criteria

Most contracts require pre-authorization approval of Denosumab Products for Malignancy-Related Indications prior to coverage.

I. Continuation of therapy (COT): Denosumab Products for Malignancy-Related Indications may be considered medically necessary for COT when criterion A, B, or C below is met.

A. For diagnoses NOT listed in the coverage criteria below, criteria 1 through 3 must be met:

1. The patient was established on therapy prior to current health plan membership AND there is documentation that the medication was covered by another health plan. Examples of documentation include the coverage approval letter from the previous health plan or paid claim.

AND

2. There is documentation of clinical benefit, such as disease stability as detailed in the reauthorization criteria.

AND

3. **For Aukelso (denosumab-kyqq)**, **Bomyntra (denosumab-bnht)**, **Jubereq (denosumab-desu)**, **Osenvelt (denosumab-bmwo)**, **Oziltus (denosumab-mobz)**, **Xgeva (denosumab)**, **and Xtrenbo (denosumab-qbde) only**: There is documented intolerance or contraindication to Bilprevda (denosumab-nxxp) and Wyost (denosumab-bbdz).

OR

B. For diagnoses listed in the coverage criteria below, criteria 1 through 3 must be met:

1. The patient was established on therapy prior to current health plan membership AND attestation that the medication was covered by another health plan.

AND

2. There is documentation of clinical benefit, such as disease stability as detailed in the reauthorization criteria.

AND

3. **For Aukelso (denosumab-kyqq)**, **Bomyntra (denosumab-bnht)**, **Jubereq (denosumab-desu)**, **Osenvelt (denosumab-bmwo)**, **Oziltus (denosumab-mobz)**, **Xgeva (denosumab)**, **and Xtrenbo (denosumab-qbde) only**: There is documented intolerance or contraindication to Bilprevda (denosumab-nxxp) and Wyost (denosumab-bbdz).

OR

C. The medication was initiated for acute disease management, as part of an acute unscheduled, inpatient hospital admission.

***Please note**: Medications obtained as samples, coupons, or promotions, paying cash for a prescription ("out-of-pocket") as an eligible patient, or any other method of obtaining medications outside of an established health plan benefit (from your insurance) does NOT necessarily establish medical necessity. Medication policy criteria apply for coverage, per the terms of the member contract with the health plan.*

II. New Starts (treatment-naïve patients): Denosumab Products for Malignancy-Related Indications may be considered medically necessary when there is clinical documentation (such as chart notes) that criteria A and B are met.

A. **For Aukelso (denosumab-kyqq)**, **Bomyntra (denosumab-bnht)**, **Jubereq (denosumab-desu)**, **Osenvelt (denosumab-bmwo)**, **Oziltus (denosumab-mobz)**, **Xgeva (denosumab)**, **and Xtrenbo (denosumab-qbde) only**: There is a documented intolerance or contraindication to Bilprevda (denosumab-nxxp) and Wyost (denosumab-bbdz).

AND

B. There is clinical documentation that criterion 1, 2, or 3 is met.

1. Prevention of **skeletal related events** (SRE; such as fractures) in patients with:

a. Bone metastases from any solid tumor or multiple myeloma.

AND

b. Prior treatment with an IV bisphosphonate [e.g., pamidronate or Zometa (zoledronic acid)] has been ineffective, contraindicated, or not tolerated.

PLEASE NOTE: Ineffective is defined as having a skeletal related event while on bisphosphonate therapy. Cancer progression is NOT considered a lack of efficacy. A contraindication to IV bisphosphonates may include, but is not limited to, creatinine clearance of less than 35 ml/min.

OR

2. Treatment of **giant cell tumor of the bone** when:

a. The tumor is unresectable.

OR

b. The tumor is resectable, but surgical resection is documented as medically contraindicated.

OR

3. Treatment of **hypercalcemia of malignancy** when:

a. The albumin-corrected calcium is above 12.5 mg/dL (3.1 mmol/L) (see *Appendix 1).*

AND

b. Prior treatment with an IV bisphosphonate [e.g., pamidronate or Zometa (zoledronic acid)] has been ineffective, contraindicated, or not tolerated.

***PLEASE NOTE**: Ineffective is defined as having persistent hypercalcemia despite bisphosphonate therapy. Cancer progression is NOT considered a lack of efficacy. A contraindication to IV bisphosphonates may include, but is not limited to, creatinine clearance of less than 35 ml/min.*

III. Administration, Quantity Limitations, and Authorization Period

A. Regence Pharmacy Services considers Denosumab Products for Malignancy-Related Indications coverable only under the medical benefit (as a provider-administered medication).

B. When pre-authorization is approved Denosumab Products for Malignancy-Related Indications may be authorized:

1. In quantities up to 13 of the 120 mg injections per year for the prevention of complications of bone metastases (SREs) from solid tumor cancers or multiple myeloma.

2. In quantities up to 15 of the 120 mg injections per year for the treatment of giant cell tumor of the bone and hypercalcemia of malignancy.

C. Authorization **may** be reviewed at least annually. Clinical documentation (such as chart notes) must be provided to confirm that current medical necessity criteria are met, and that the medication is providing clinical benefit, such as disease stability or improvement.

IV. Denosumab Products for Malignancy-Related Indications are considered not medically necessary for the treatment of osteoporosis.

V. Denosumab Products for Malignancy-Related Indications are considered investigational when used for all other conditions.

Position Statement

Summary

- Denosumab is a monoclonal antibody used for the prevention of skeletal related events (SREs) in patients with bone metastases from solid tumor cancers (e.g., breast cancer, prostate cancer) or multiple myeloma. It is also used for the treatment of giant cell tumor of the bone and hypercalcemia of malignancy.
- Generic IV bisphosphonates (pamidronate and zoledronic acid) provide the best value for prevention of SREs such as fractures in patients with solid tumors or multiple myeloma.
- There is insufficient evidence of superior safety or tolerability of denosumab over bisphosphonates. Both have a risk of osteonecrosis of the jaw (ONJ).
- There is reliable evidence that denosumab is a potent antiresorptive therapy for the prevention of SREs in patients with some cancers. The effect is consistent across the placebo-controlled trials and comparative, non-inferiority trials. However, there is uncertainty in the evidence with regard to whether denosumab is better than other available treatment options.
- Denosumab and zoledronic acid (generic Zometa) appear to be at least similar in delaying the time to first SRE in patients with metastases from solid tumor cancers; however, the clinical relevance of delaying the time to first SRE is uncertain relative to prevention of SREs, reduction in the number of SREs, or overall survival.
- The evidence for efficacy for denosumab for the treatment of giant cell tumor of the bone comes from two open-label trials that demonstrated a decrease in tumor size in 25% of patients. Patients in the trials had e giant cell tumor of the bone that was either recurrent, unresectable, or for which planned surgery was likely to result in severe morbidity.
- The evidence for efficacy for denosumab for hypercalcemia of malignancy comes from a single-arm trial in patients refractory to treatment with prior IV bisphosphonate therapy. Denosumab was associated with lowering corrected serum calcium 63.6% of patients treated at day ten.
- FDA-approved biosimilar medications are not meaningfully different clinically than their reference products (i.e., therapeutically equivalent). Although small differences in clinically inactive portions of the molecule may exist, the FDA approval certifies that the manufacturer has shown their product to be identical in function. There is no scientific basis to prefer one FDA-approved product over another (reference product or biosimilar). Given similar efficacy and safety, most contracts consider more costly products not medically necessary.
- Among all denosumab products in this policy, Bilprevda (denosumab-nxxp) and Wyost (denosumab-bbdz) offer the best value for health plan members.
- The recommended dose of denosumab for prevention of skeletal-related events in multiple myeloma and bone metastasis from solid tumors is 120 mg every four weeks. For giant cell tumor of the bone and hypercalcemia of malignancy, the recommended dose is 120 mg every four weeks with additional 120 mg doses given on days 8 and 15 of the first month of therapy.

Regence Pharmacy Services performs independent analyses of oncology medication evidence, to establish coverability per the contracts with the health plan.

- Most contracts define coverability based on established clinical benefit in published, peer-reviewed literature, along with consideration of regulatory status.
- FDA approval does not in itself establish medical necessity, as unpublished, low-quality evidence, including exploratory analyses and unvalidated surrogate endpoints, may be used as the basis of approval. Regulatory approval may or may not reflect clinical benefit relative to standard of care and the recommendations of expert clinical advisors such as the Oncologic Drugs Advisory Committee (ODAC). FDA approvals generally do not consider cost compared to established therapies, or value to members.
- Likewise, NCCN clinical practice guidelines assignment of a recommendation (category 1, 2a, or 2b) does not necessarily establish medical necessity. NCCN recommendations are inconsistently supported by published, peer-reviewed literature and do not uniformly consider value of new therapies relative to existing equally efficacious potentially higher-value treatment options, considering effectiveness, safety, and cost. NCCN is a CMS recognized compendium that is considered a reference standard, rather than a gold standard, of care. NCCN compendia are not strictly evidence-based and therefore may not be supported by the best available evidence or meet benefit contract definitions of medical necessity. Medication coverage criteria are developed based on the 'medical necessity' assessment, as described above.

Regence Pharmacy Services analysis and coverage policy may differ from FDA labeled indication and/or NCCN clinical practice guidelines.

Clinical Efficacy

CANCER-RELATED BONE METASTASES

Metastatic Breast and Prostate Cancer

- The effectiveness of denosumab for bone metastases from breast or prostate cancer relative to zoledronic acid was evaluated in two low confidence, randomized, double-blind, non-inferiority trials that included 2,046 women with bone metastases from breast cancer and 1,904 men with metastatic prostate cancer. [1 2]
    - The primary endpoint in both trials was the non-inferiority of denosumab relative to zoledronic acid for time to first SRE (defined as bone pain, pathologic fractures, spinal cord compression, and bone complications that required radiation or surgery).

Breast Cancer

- Denosumab was shown to be at least similar to zoledronic acid for delaying the time to first SRE in patients with metastatic breast cancer and metastatic prostate cancer. The study authors concluded that denosumab was superior to zoledronic acid for delaying time to first SRE; however, the evidence is of insufficient quality to validate that conclusion. There was no difference between treatment groups for overall survival or disease progression. [2]

- The National Comprehensive Cancer Network (NCCN) Breast Cancer guideline recommends that denosumab, zoledronic acid, or pamidronate (all with calcium and vitamin D supplementation) should be given in addition to chemotherapy or endocrine therapy if bone metastasis is present. There is no preference given to one agent over the other, as all are considered a category 1 recommendation. [3]
- The American Society of Clinical Oncology (ASCO) guideline recognizes denosumab, pamidronate, and zoledronic acid as treatment options for patients with breast cancer with evidence of bone metastases. Per the ASCO guideline, there is insufficient evidence to demonstrate greater efficacy of one product over another for the prevention and treatment of skeletal-related events. [4]

Prostate Cancer

- There is low confidence in the evidence that denosumab is superior to zoledronic acid because the clinical relevance of delaying the time to first SRE is uncertain, particularly in the absence of improved overall survival or disease progression. Additional concerns with the studies include high attrition and the potential for suboptimal dosing of zoledronic acid. [1]
- The NCCN Prostate Cancer guideline recommends both zoledronic acid (category 2A recommendation) and denosumab (category 1 recommendation) for the prevention of skeletal-related events in patients with prostate cancer if bone metastases is present. [5] However, there is low confidence in the evidence that denosumab is superior to zoledronic acid.

Other Solid Tumor Cancers and Multiple Myeloma

- The effectiveness of denosumab relative to zoledronic acid was evaluated in a low confidence, randomized, double-blind, non-inferiority trial that included 1,779 patients with bone metastases from various advanced solid tumor cancers (excluding breast or prostate cancer) or patients with multiple myeloma. [6]
    * The primary endpoint was the non-inferiority of denosumab relative to zoledronic acid for time to first SRE.
    * Denosumab was shown to be non-inferior to zoledronic acid for time to first SRE. There was no difference between treatment groups for overall survival or disease progression.
    * The trial is considered low confidence because the clinical relevance of delaying the time to first SRE is uncertain, particularly in the absence of improved overall survival or disease progression. Additional concerns with the study include high attrition and the potential for suboptimal dosing of zoledronic acid.
    * In a subgroup analysis of patients with multiple myeloma (n = 180), an increase in mortality was observed with denosumab relative to zoledronic acid. [7] A follow-up non-inferiority trial demonstrated the non-inferiority of denosumab compared to zoledronic acid. No difference in mortality was observed. [7]

GIANT CELL TUMOR OF THE BONE:

- The safety and efficacy of denosumab was evaluated in 282 adult or skeletally mature adolescent patients with giant cell tumor of the bone.
    * Two open-label, uncontrolled trials studied denosumab in patients with giant cell tumor of the bone that was recurrent, unresectable, or for which surgery would likely result in morbidity. [8 9]
    * Objective response rate (decrease in tumor size) was evaluated as the primary efficacy endpoint. The overall objective response rate was 25%, and all responses were partial responses. [7-9]
- The NCCN Bone Cancer guideline recognizes denosumab as a category 2A recommendation for giant cell bone tumors that are unresectable or are resectable with unacceptable morbidity. Interferon, peg-interferon, radiation therapy, and observation are also listed as category 2A recommendations in these treatment settings. [10]

HYPERCALCEMIA OF MALIGNANCY:

- The safety and efficacy of denosumab was demonstrated in an open-label, single-arm trial in 33 patients with hypercalcemia of malignancy (with or without bone metastases). [7 11]
    * Patients were refractory to treatment with IV bisphosphonate therapy. Refractory hypercalcemia of malignancy was defined as albumin-corrected calcium of > 12.5 mg/dL (3.1 mmol/L) despite treatment with IV bisphosphonate in the seven to thirty days prior to initiation of denosumab therapy.
    * The primary outcome measure was the proportion of patients achieving a response, defined as corrected serum calcium ≤ 11.5 mg/dL (2.9 mmol/L), within ten days after denosumab administration.
    * A total of 21 out of 33 patients (64%) had a response to denosumab treatment within ten days.

Investigational Uses

- Denosumab is also marketed as Prolia (and corresponding biosimilars) and is indicated for the treatment of osteoporosis. Use of Denosumab Products for Malignancy-Related Indications for osteoporosis is considered not medically necessary as dosage and frequency of administration differ between indications and products.
- The use of denosumab for all other conditions is considered investigational.

Safety [7]

- Both bisphosphonates and denosumab have labeled warnings for risk of osteonecrosis of the jaw (ONJ).
    * As noted in the NCCN prostate cancer and breast cancer guidelines, ONJ is seen with both denosumab and bisphosphonates.
    * Poor baseline dental health or dental procedures during treatment are known risk factors for ONJ. Thus, patients should be referred for dental evaluation before starting either agent.
    * A position paper from the American Association or Oral and Maxillofacial Surgeons (AAOMS) states that the risk for ONJ among cancer patients exposed to denosumab is comparable to the risk of ONJ in patients exposed to zoledronic acid. [12]
- Denosumab can cause severe symptomatic hypocalcemia, and fatal events have occurred. All patients should be adequately supplemented with calcium and vitamin D when appropriate.

Biosimilars and Reference Products[13 14]

- FDA-approved biosimilar medications are not meaningfully different clinically than their reference products (i.e., therapeutically equivalent). Although small differences in clinically inactive portions of the molecule may exist, the FDA approval certifies that the manufacturer has shown their product to be identical in function. There is no scientific basis to prefer one FDA-approved product over another; given similar efficacy and safety, most contracts consider more costly products not medically necessary.
- Preferred products offer a less costly alternative to non-preferred products. Biosimilars are considered to be equally effective as their reference products.
    * There is no evidence that any one product (biosimilars vs. reference products) is safer or more effective than another.
    * Preferred products provide the best value for health plan members.
    * Pricing between individual products is variable and the lowest net cost products are available for coverage
- Coverage of services for members enrolled in clinical trials is provided, consistent with current standards of care. FDA-approved biosimilars are not clinically different from reference products. Biosimilars use has been endorsed by national guidelines. Non-preferred products which are more costly than preferred products may be provided by study sponsors.
- Hospitals and health-systems have medication formularies developed independent of the health plan. The health plan is unable to cover more expensive products for the convenience of the hospital, health-system, provider, or member. Preferred products represent the lowest cost to members and the health plan; the use of more expensive products without evidence of superior efficacy or safety is not medically necessary per the member's contract.

Appendix 1: Equation for Determining Albumin-Corrected Calcium

Calcium Correction Equation
Corrected Calcium = Serum Ca + 0.8 * (Normal Albumin – Patient Albumin) [a,b] Corrected Calcium Calculators: http://www.globalrph.com/calcium.htm http://www.uptodate.com/contents/calculator-calcium-correction-in-hypoalbuminemia (with subscription)

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Cross References
Prolia, denosumab, BlueCross BlueShield Association Specialty Pharmacy Combined Capacity (SPCC) Report # 8. July 2010.
Xgeva, denosumab, BlueCross BlueShield Association Specialty Pharmacy Combined Capacity (SPCC) Report # 15-2010. December 2010.
Denosumab Products for Osteoporosis, Medication Policy Manual, Policy No. dru223
Anabolic Bone Medications, Medication Policy Manual, Policy No, dru612

Codes	Number	Description
HCPCS	Q5161	Injection, denosumab-kyqq (Aukelso), biosimilar, 1 mg
HCPCS	Q5162	Injection, denosumab-nxxp (Bilprevda), biosimilar, 1 mg
HCPCS	Q5158	Injection, denosumab-bnht (Bomyntra, Conexxence), biosimilar, 1 mg
HCPCS	Q5136	Injection, denosumab-bbdz (Jubbonti, Wyost), biosimilar, 1 mg
HCPCS	Q5157	Injection, denosumab-bmwo (Osenvelt, Stoboclo), biosimilar, 1 mg
HCPCS	J0897	Injection, denosumab (Prolia, Xgeva), 1 mg

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Revision History

Revision Date	Revision Summary
4/2/2026	Added new biosimilars Jubereq (denosumab-desu) and Oziltus (denosumab-mobz) to policy as non-preferred.
1/22/2026	• Added new biosimilars Aukelso (denosumab-kyqq) and Xtrenbo (denosumab-qbde) to policy as non-preferred. • Changed Bilprevda (denosumab-nxxp) to preferred.
10/2/2025	Added new biosimilar Bilprevda (denosumab-nxxp) as non-preferred.
7/10/2025	• Added new biosimilars Bomyntra (denosumab-bnht), Osenvelt (denosumab-bmwo), and Wyost (denosumab-bbdz) and renamed policy. • Added step through Wyost (denosumab-bbdz) for Bomyntra (denosumab-bnht), Osenvelt (denosumab-bmwo), and Xgeva (denosumab) new starts and continuation of therapy criteria.
09/19/2024	No criteria changes with this annual review.
9/14/2023	No criteria changes with this annual review.
9/23/2022	No criteria changes with this annual update.
10/15/2021	Updated COT. No criteria changes with this annual update.
10/28/2020	Added COT criteria. No change to intent of policy.
10/23/2019	Clarification of policy language (no changes to criteria intent with this annual update)
1/18/2018	Coverage criteria for prevention of skeletal-related events in multiple myeloma added.
3/10/2017	No criteria changes with this annual update.
3/11/2016	No criteria changes with this annual update.

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