Corporate Medical Policy: Denosumab (Prolia®, Xgeva®) and Denosumab Biosimilars **"Notification"** **POLICY EFFECTIVE APRIL 1, 2026**

Restricted Product(s):

- denosumab (Prolia®) subcutaneous injection for administration by a healthcare professional
- denosumab (Xgeva®) subcutaneous injection for administration by a healthcare professional
- *denosumab-bbdz (Jubbonti®) subcutaneous injection for administration by a healthcare professional
- *denosumab-bbdz (Wyost®) subcutaneous injection for administration by a healthcare professional
- *denosumab-bmwo (Stoboclo®) subcutaneous injection for administration by a healthcare professional
- *denosumab-bmwo (Osenvelt®) subcutaneous injection for administration by a healthcare professional
- denosumab-bnht (Conexxence®) subcutaneous injection for administration by a healthcare professional
- denosumab-bnht (Bomyntra®) subcutaneous injection for administration by a healthcare professional
- denosumab-desu (Osvyrti®) subcutaneous injection for administration by a healthcare professional
- denosumab-desu (Jubereq®) subcutaneous injection for administration by a healthcare professional
- denosumab-dssb (Ospomyv®) subcutaneous injection for administration by a healthcare professional
- denosumab-dssb (Xbryk®) subcutaneous injection for administration by a healthcare professional
- denosumab-kyqq (Bosaya®) subcutaneous injection for administration by a healthcare professional
- denosumab-kyqq (Aukelso®) subcutaneous injection for administration by a healthcare professional
- denosumab-mobz (Boncresa®) subcutaneous injection for administration by a healthcare professional
- denosumab-mobz (Oziltus®) subcutaneous injection for administration by a healthcare professional
- *denosumab-nxxp (Bildyos®) subcutaneous injection for administration by a healthcare professional
- *denosumab-nxxp (Bilprevda®) subcutaneous injection for administration by a healthcare professional
- denosumab-qbde (Enoby®) subcutaneous injection for administration by a healthcare professional
- denosumab-qbde (Xtrenbo®) subcutaneous injection for administration by a healthcare professional

***preferred agent(s)**

FDA Approved Use:

- Denosumab (Prolia®), Denosumab-bbdz (Jubbonti®), Denosumab-bmwo (Stoboclo®), Denosumab-bnht (Conexxence®), Denosumab-desu (Osvyrti®), Denosumab-dssb (Ospomyv®), Denosumab-kyqq (Bosaya®), Denosumab-mobz (Boncresa®), Denosumab-nxxp (Bildyos®), Denosumab-qbde (Enoby®)
    - Treatment of postmenopausal women with osteoporosis at high risk for fracture

- Treatment to increase bone mass in men with osteoporosis at high risk for fracture
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

- Denosumab (Xgeva®), Denosumab-bbdz (Wyost®), Denosumab-bmwo (Osenvelt®), Denosumab-bnht (Bomyntra®), Denosumab-desu (Jubereq®), Denosumab-dssb (Xbryk®), Denosumab-kyqq (Aukelso®), Denosumab-mobz (Oziltus®), Denosumab-nxxp (Bilprevda®), Denosumab-qbde (Xtrenbo®)
  - 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

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The request is for **Prolia (denosumab)**, **Bildyos (denosumab-nxxp)**, **Boncresa (denosumab-mobz)**, **Bosaya (denosumab-kyqq)**, **Conexxence (denosumab-bnht)**, **Enoby (denosumab-qbde)**, **Jubbonti (denosumab-bbdz)**, **Ospomyv (denosumab-dssb)**, **Osvyrti (denosumab-desu)**, or **Stoboclo (denosumab-bmwo)**; **AND**
   a. The patient is 18 years of age or older; **AND**
   b. The patient has a diagnosis of **osteoporosis**; **AND**
      i. ONE of the following:
         1. The patient is a male over 50 years old; **OR**
         2. The patient is a postmenopausal female; **AND**
      ii. The patient is at high risk for fracture defined by ONE of the following:
         1. History of osteoporotic fracture; **OR**
         2. Multiple risk factors for fracture; **AND**
      iii. ONE of the following:
         1. The patient has previously been treated with a bisphosphonate and experienced a therapeutic failure or inadequate response; **OR**
         2. The patient is unable to receive a bisphosphonate due to a contraindication/hypersensitivity; **OR**

c. The patient has a diagnosis of **breast cancer**; **AND**
    i. The patient is currently receiving aromatase inhibitor therapy (e.g., anastrozole, letrozole, exemestane) for breast cancer; **AND**
    ii. ONE of the following:
        1. The patient has previously been treated with a bisphosphonate and experienced a therapeutic failure or inadequate response; **OR**
        2. The patient is unable to receive a bisphosphonate due to a contraindication/hypersensitivity; **OR**
d. The patient has a diagnosis of **nonmetastatic prostate cancer**; **AND**
    i. The patient is currently receiving androgen deprivation therapy; **AND**
    ii. ONE of the following:
        1. The patient has previously been treated with a bisphosphonate and experienced a therapeutic failure or inadequate response; **OR**
        2. The patient is unable to receive a bisphosphonate due to a contraindication/hypersensitivity; **OR**
e. The patient has been diagnosed with **glucocorticoid-induced osteoporosis**; **AND**
    i. The patient is at high risk for fracture defined by ONE of the following:
        1. History of osteoporotic fracture; **OR**
        2. Multiple risk factors for fracture; **AND**
    ii. The patient is initiating or continuing systemic glucocorticoids in a daily dosage equal to 7.5 mg or greater of prednisone and expected to remain on therapy for at least 6 months; **AND**
    iii. ONE of the following:
        1. The patient has previously been treated with a bisphosphonate and experienced a therapeutic failure or inadequate response; **OR**
        2. The patient is unable to receive a bisphosphonate due to a contraindication/hypersensitivity; **AND**
f. If the request is for Prolia (denosumab), Boncresa (denosumab-mobz), Bosaya (denosumab-kyqq), Conexxence (denosumab-bnht), Enoby (denosumab-qbde), Ospomyv (denosumab-dssb), Osvyrti (denosumab-desu), or a non-preferred denosumab product, ONE of the following:
    i. The patient has tried and had an inadequate response to ALL of the following preferred denosumab biosimilar products: Bildyos (denosumab-nxxp), Jubbonti (denosumab-bbdz), AND Stoboclo (denosumab-bmwo) **[medical record documentation required]**; **OR**
    ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to Bildyos (denosumab-nxxp), Jubbonti (denosumab-bbdz), AND Stoboclo (denosumab-bmwo) that is NOT expected to occur with the requested agent **[medical record documentation required]**; **OR**

iii. The patient has a documented serious adverse event that required medical intervention to Bildyos (denosumab-nxxp), Jubbonti (denosumab-bbdz), AND Stoboclo (denosumab-bmwo) that is NOT anticipated with the requested agent **[medical record documentation required]**; **AND**
    1. The prescriber has completed and submitted an FDA MedWatch Adverse Event Reporting Form **[medical record documentation required]**; **OR**

2. The request is for **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)**, or **Xtrenbo (denosumab-qbde)**; **AND**
    a. The patient has a diagnosis of **multiple myeloma**; **AND**
        i. The requested agent will be used for prevention of skeletal-related events; **AND**
        ii. ONE of the following:
            1. The patient has had prior treatment with an intravenous bisphosphonate and experienced a therapeutic failure or inadequate response; **OR**
            2. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to intravenous bisphosphonate therapy; **OR**
    b. The patient has a **solid tumor cancer diagnosis** (other than breast cancer, lung cancer, or castration-resistant prostate cancer) (e.g., thyroid cancer, kidney cancer) AND has documented bone metastases; **AND**
        i. The requested agent will be used for prevention of skeletal-related events; **AND**
        ii. ONE of the following:
            1. The patient has had prior treatment with an intravenous bisphosphonate and experienced a therapeutic failure or inadequate response; **OR**
            2. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to intravenous bisphosphonate therapy; **OR**
    c. The patient has a diagnosis of **giant cell tumor of bone**; **AND**
        i. The patient is an adult or skeletally mature adolescent (12 years of age or older); **AND**
        ii. ONE of the following:
            1. The tumor is recurrent; **OR**
            2. The tumor is unresectable; **OR**
            3. Surgical resection is likely to result in severe morbidity; **OR**
    d. The patient has a diagnosis of **hypercalcemia of malignancy**; **AND**

i. The patient has had prior treatment with an intravenous bisphosphonate and experienced a therapeutic failure or inadequate response; **OR**
ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to intravenous bisphosphonate therapy; **OR**

e. The patient has a diagnosis of **breast cancer** AND has documented bone metastases; **OR**
f. The patient has a diagnosis of **lung cancer** AND has documented bone metastases; **OR**
g. The patient has a diagnosis of **castration-resistant prostate cancer** AND has documented bone metastases; **OR**
h. The patient has a diagnosis of **systemic mastocytosis**; **AND**
    i. The patient has had prior treatment with an intravenous bisphosphonate and experienced a therapeutic failure or inadequate response; **OR**
    ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to intravenous bisphosphonate therapy; **AND**
i. If the request is for Xgeva (denosumab), Aukelso (denosumab-kyqq), Bomyntra (denosumab-bnht), Jubereq (denosumab-desu), Oziltus (denosumab-mobz), Xbryk (denosumab-dssb), Xtrenbo (denosumab-qbde), or a non-preferred denosumab product, ONE of the following:
    i. The patient has tried and had an inadequate response to ALL of the following preferred denosumab biosimilar products: Bilprevda (denosumab-nxxp), Osenvelt (denosumab-bmwo), AND Wyost (denosumab-bbdz) **[medical record documentation required]**; **OR**
    ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to Bilprevda (denosumab-nxxp), Osenvelt (denosumab-bmwo), AND Wyost (denosumab-bbdz) that is NOT expected to occur with the requested agent **[medical record documentation required]**; **OR**
    iii. The patient has a documented serious adverse event that required medical intervention to Bilprevda (denosumab-nxxp), Osenvelt (denosumab-bmwo), AND Wyost (denosumab-bbdz) that is NOT anticipated with the requested agent **[medical record documentation required]**; **AND**
        1. The prescriber has completed and submitted an FDA MedWatch Adverse Event Reporting Form **[medical record documentation required]**; **AND**

3. The patient will NOT be using the requested agent in combination with a bisphosphonate, another form of denosumab (e.g., Prolia or Xgeva, etc.), romosozumab-aqqg, or a parathyroid hormone analog for osteoporosis (e.g., abaloparatide, teriparatide, etc.); **AND**
4. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
5. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

NOTE:
Use of Denosumab and Denosumab Biosimilars may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of **cancer** either:

1. In accordance with FDA label, when clinical benefit has been established and it is not determined to be investigational as defined in the Blue Cross NC Corporate Medical Policy (CMP), "Investigational (Experimental) Services." Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia.; **OR**
2. In accordance with specific strong endorsement or support by nationally recognized compendia (e.g., National Comprehensive Cancer Network, NCCN), when such recommendation is based on the highest level of evidence (Level 1, 2A), and/or uniform consensus of clinical appropriateness has been reached.

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
denosumab (Prolia®) subcutaneous (SC) injection	Postmenopausal osteoporosis in women at high risk for fracture	60 mg SC every 6 months	J0897	120
denosumab-bbdz (Jubbonti®) subcutaneous (SC) injection	Osteoporosis in men at high risk for fracture, to increase bone mass		Q5136	
denosumab-bmwo (Stoboclo®) subcutaneous (SC) injection	Glucocorticoid-induced osteoporosis in men and women at high risk for fracture		Q5157	
denosumab-bnht (Conexxence®) subcutaneous (SC) injection	To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer		Q5158	
denosumab-desu (Osvyrti®) subcutaneous (SC) injection	To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer		C9399** J3490** J3590**	

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
denosumab-dssb (Ospomyv®) subcutaneous (SC) injection			Q5159	
denosumab-kyqq (Bosaya®) subcutaneous (SC) injection			C9399** J3490** J3590**	
denosumab-mobz (Boncresa®) subcutaneous (SC) injection			C9399** J3490** J3590**	
denosumab-nxxp (Bildyos®) subcutaneous (SC) injection			C9399** J3490** J3590**	
denosumab-qbde (Enoby®) subcutaneous (SC) injection			C9399** J3490** J3590**	
denosumab (Xgeva®) subcutaneous (SC) injection	Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors Giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, in adults and skeletally mature adolescents	Multiple myeloma and bone metastasis from solid tumors: 120 mg SC every 4 weeks Giant cell tumor of bone: 120 mg SC every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy	J0897	Multiple myeloma: 1,560 Giant cell tumor of bone: 1,800 Hypercalcemia of malignancy: 1,800
denosumab-bbdz (Wyost®) subcutaneous (SC) injection			Q5136	
denosumab-bmwo (Osenvelt®) subcutaneous (SC) injection			Q5157	

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
denosumab-bnht (Bomyntra®) subcutaneous (SC) injection	Hypercalcemia of malignancy refractory to bisphosphonate therapy	Hypercalcemia of malignancy: 120 mg SC every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy	Q5158	Bone metastases from solid tumors: 1,560 Systemic mastocytosis: 1,560
denosumab-desu (Jubereq®) subcutaneous (SC) injection			C9399** J3490** J3590** J9999**	
denosumab-dssb (Xbryk®) subcutaneous (SC) injection			Q5159	
denosumab-kyqq (Aukelso®) subcutaneous (SC) injection			C9399** J3490** J3590** J9999**	
denosumab-mobz (Oziltus®) subcutaneous (SC) injection			C9399** J3490** J3590** J9999**	
denosumab-nxxp (Bilprevda®) subcutaneous (SC) injection			C9399** J3490** J3590** J9999**	
denosumab-qbde (Xtrenbo®) subcutaneous (SC) injection			C9399** J3490** J3590** J9999**	

***Maximum units allowed for duration of approval**
****Non-specific assigned HCPCS codes, must submit requested product NDC**

Other applicable codes may include:

ICD-10 Codes: C00.0-C49.9, C4A.0-C4A.9, C50.011-C79.9, C7A.00-C7A.8, C7B.00-C7B.8, C80.0- C86.6, C88.2-C96.Z, D00.00-D09.9, M81.0, M81.8, T50.905, Z51.11, Z51.12, Z79.811, Z87.311

For oncology use, the cancer diagnosis code must also be included when the following codes are used: M81.0, M81.8, T50.905, Z79.811, Z87.311

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of a severe adverse event following the injection or infusion of the requested medication (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**
    b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**
    c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
    d. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
    e. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
    f. Re-initiation of therapy, defined as ONE of the following:
        i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
        ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
    g. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Ellis GK, Bone HG, Chlebowski R, et al. Randomized trial of denosumab in patients receiving adjuvant aromatase inhibitors for nonmetastatic breast cancer. 2008 Oct;26:4875-4882.
2. McClung MR, Lewiecki EM, Cohen SB, et al. Denosumab in postmenopausal women with low bone mineral density. *N Engl J Med*. 2006; 354:821-831.

3. North American Menopause Society (NAMS). Management of osteoporosis in postmenopausal women: 2010 position statement of The North American Menopause Society. *Menopause*. 2010:17(1):25-54.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

April 2026: Criteria change: Changed requirement for trial and failure of preferred denosumab (Prolia) biosimilar products to include Bildyos in addition to existing preferred Jubbonti and Stoboclo; adjusted non-preferred denosumab (Prolia) biosimilar products to include Prolia, Boncresa, Bosaya, Conexxence, Enoby, Ospomyv, and Osvyrti. Changed requirement for trial and failure of preferred denosumab (Xgeva) biosimilar products to include Bilprevda in addition to existing preferred Osenvelt and Wyost; adjusted non-preferred denosumab (Xgeva) biosimilar products to include Xgeva, Aukelso, Bomyntra, Jubereq, Oziltus, Xbryk, and Xtrenbo. Added Site of Care medical necessity criteria. **Policy notification given 2/1/2026 for effective date 4/1/2026**.
January 2026v2: Criteria change: For Xgeva and Xgeva biosimilar products, removed required trial and failure of IV bisphosphonate from bone metastases secondary to breast cancer and from bone metastases secondary to lung cancer within the solid tumor cancer diagnosis criteria. Added new to market Prolia (denosumab) biosimilar Boncresa (denosumab-mobz) to policy for the same FDA approved indications as Prolia and with the same coverage criteria requirements; and added additional corresponding criteria as a non-preferred denosumab product with requirement of trial and failure of both Jubbonti AND Stoboclo (preferred denosumab biosimilar products), or presence of a documented serious adverse event requiring medical intervention from both preferred denosumab biosimilar products that is not anticipated with the requested non-preferred denosumab product, with required submission of an FDA MedWatch Adverse Event Reporting Form. Added new to market Xgeva (denosumab) biosimilar Oziltus (denosumab-mobz) to policy for the same FDA approved indications as Xgeva and with the same coverage criteria requirements; and additional corresponding criteria as a non-preferred denosumab product with requirement of trial and failure of both Osenvelt AND Wyost (preferred denosumab biosimilar products), or presence of a documented serious adverse event requiring medical intervention from both preferred denosumab biosimilar products that is not anticipated with the requested non-preferred denosumab product, with required submission of an FDA MedWatch Adverse Event Reporting Form. Updated FDA label reference table with addition of new to market products and maximum units for bone metastases from solid tumors and systemic mastocytosis.
January 2026: Criteria change: Added new to market Prolia (denosumab) biosimilars Enoby (denosumab-qbde) and Osvyrti (denosumab-desu) to policy for the same FDA approved indications as Prolia and with the same coverage criteria requirements; and added additional corresponding criteria as a non-preferred denosumab product with requirement of trial and failure of both Jubbonti AND Stoboclo (preferred denosumab biosimilar products), or presence of a documented serious adverse event requiring medical intervention from both preferred denosumab biosimilar products that is not anticipated with the requested non-preferred denosumab product, with required submission of an FDA MedWatch Adverse Event Reporting Form. Added new to market Xgeva (denosumab) biosimilars Jubereq (denosumab-desu) and Xtrenbo (denosumab-qbde) to policy for the same FDA approved indications as Xgeva and with the same coverage criteria requirements; and additional corresponding criteria as a non-preferred denosumab product with requirement of trial and failure of both Osenvelt AND

Wyost (preferred denosumab biosimilar products), or presence of a documented serious adverse event requiring medical intervention from both preferred denosumab biosimilar products that is not anticipated with the requested non-preferred denosumab product, with required submission of an FDA MedWatch Adverse Event Reporting Form. Updated FDA label reference table with addition of new to market products.
January 2026: Criteria change: Added new to market Prolia (denosumab) biosimilars Bildyos (denosumab-nxxp) and Bosaya (denosumab-kyqq) to policy for the same FDA approved indications as Prolia and with the same coverage criteria requirements. For Prolia, Bildyos, Bosaya, Conexxence, and Ospomyv: added additional corresponding criteria as a non-preferred denosumab product with requirement of trial and failure of both Jubbonti AND Stoboclo (preferred denosumab biosimilar products), or presence of a documented serious adverse event requiring medical intervention from both preferred denosumab biosimilar products that is not anticipated with the requested non-preferred denosumab product, with required submission of an FDA MedWatch Adverse Event Reporting Form. Added new to market Xgeva (denosumab) biosimilars Aukelso (denosumab-kyqq) and Bilprevda (denosumab-nxxp) to policy for the same FDA approved indications as Xgeva and with the same coverage criteria requirements. For Xgeva, Aukelso, Bilprevda, Bomyntra, and Xbryk: added additional corresponding criteria as a non-preferred denosumab product with requirement of trial and failure of both Osenvelt AND Wyost (preferred denosumab biosimilar products), or presence of a documented serious adverse event requiring medical intervention from both preferred denosumab biosimilar products that is not anticipated with the requested non-preferred denosumab product, with required submission of an FDA MedWatch Adverse Event Reporting Form. For Xgeva and Xgeva biosimilar products: added requirement of trial and failure of an IV bisphosphonate to multiple myeloma and solid tumor with bone metastases indications; added indication for breast cancer with bone metastases with requirement of trial and failure of an IV bisphosphonate; added indication for castration-resistant prostate cancer with bone metastases; added indication for systemic mastocytosis with requirement of trial and failure of an IV bisphosphonate. For all restricted products and indications, added requirement of no use in combination with a bisphosphonate, another form of denosumab (e.g., Prolia or Xgeva), romosozumab-aqqg, or a parathyroid hormone analog for osteoporosis. Adjusted maximum units for oncologic indications according to FDA labeled dosing. Consolidated FDA label reference table for clarity. Other minor formatting adjustments made throughout policy for clarity. **Policy notification given 10/1/2025 for effective date 1/1/2026**.
October 2025: Coding change: For denosumab-bmwo (Stoboclo/Osenvelt), added HCPCS code Q5157 (1 unit per 1 mg) to dosing reference table effective 10/1/2025; deleted C9399, J3490, J3590, and J9999 termed 9/30/2025. For denosumab-bnht (Bomyntra/Conexxence), added HCPCS code Q5158 (1 unit per 1 mg) to dosing reference table effective 10/1/2025; deleted C9399, J3490, J3590, and J9999 termed 9/30/2025. For denosumab-dssb (Ospomyv/Xbryk), added HCPCS code Q5159 (1 unit per 1 mg) to dosing reference table effective 10/1/2025; deleted C9399, J3490, J3590, and J9999 termed 9/30/2025.
October 2025: Criteria change: For Conexxence, Jubbonti, Ospomyv, and Stoboclo, removed requirement of trial and failure of Prolia. For Bomyntra, Osenvelt, Wyost, and Xbryk, removed requirement of trial and failure of Xgeva.
June 2025: Criteria change: Added new to market Prolia (denosumab) biosimilars Conexxence (denosumab-bnht), Jubbonti (denosumab-bbdz), Ospomyv (denosumab-dssb), and Stoboclo (denosumab-bmwo) to policy for the same FDA approved indications as Prolia and with the same coverage criteria requirements. For Conexxence, Jubbonti, Ospomyv, and Stoboclo, added additional corresponding criteria as a non-preferred Prolia (denosumab) biosimilar product with requirement of trial and failure of Prolia. Added new to market Xgeva (denosumab)

biosimilars Bomyntra (denosumab-bnht), Osenvelt (denosumab-bmwo), Wyost (denosumab-bbdz), and Xbryk (denosumab-dssb) to policy for the same FDA approved indications as Xgeva and with the same coverage criteria requirements. For Bomyntra, Osenvelt, Wyost, and Xbryk, added additional corresponding criteria as a non-preferred Xgeva (denosumab) biosimilar product with requirement of trial and failure of Xgeva. Added associated dosing, maximum units, and HCPCS codes (Q5136 [Jubbonti/Wyost], C9399, J3490, and J3590 [for Conexxence, Ospomyv, and Stoboclo], C9399, J3490, J3590, and J9999 [for Bomyntra, Osenvelt, and Xbryk]) to FDA label reference table. Changed policy name to “Denosumab (Prolia®, Xgeva®) and Denosumab Biosimilars” from “Denosumab (Prolia®, Xgeva®)”. Adjusted maximum units for oncology indications to 9999 to indicate unlimited units for clarity. Other minor adjustments made to formatting of FDA label reference table for clarity with no change to intent.
June 2021: Criteria change: Added trial and failure or contraindication /hypersensitivity to a bisphosphonate for patients with breast cancer or prostate cancer at high risk for fracture; added maximum units; medical policy formatting change. **Policy notification given 4/16/2021 for effective date 6/16/2021**.
*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.