

Medical Policy:

Denosumabs

Last review date: 10/01/2026

Prior review date: 08/24/2026

Applicable Products:	
Prolia (denosumab) Prolia Biosimilars: - Jubbonti® (denosumab-bbdz) - Stoboclo® (denosumab-bmwo) - Conexence® (denosumab-bnht) - Bildyos® (denosumab-nxxp) - Osvyrti® (denosumab-desu) - Bosaya® (denosumab-kyqq) - Enoby® (denosumab-qbde) - Boncresa® (denosumab-mobz) - Ponlimsi® (denosumab-adet) - Ospomyv® (denosumab-dssb)	Xgeva (denosumab) Xgeva Biosimilars: - Wyost® (denosumab-bbdz) - Osenvelt® (denosumab-bmwo) - Bomyntra® (denosumab-bnht) - Bilprevda® (denosumab-nxxp) - Jubereq® (denosumab-desu) - Aukelso® (denosumab-kyqq) - Xtrenbo® (denosumab-qbde) - Oziltus® (denosumab-mobz)

Initial Approval Criteria:

Coverage may be approved if all the following are met:

- Drug-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Prolia and biosimilars

- The patient must be 18 years of age or older; **AND**
- Must be prescribed by or in consultation with a provider; **AND**
- Patient is not taking Xgeva or an Xgeva biosimilar while taking this medication; **AND**
- Patient must have a diagnosis of one of the following:
 - Postmenopausal Osteoporosis (PMO)
 - Patient must be 18 years of age or older; **AND**
 - Patient is at very high risk for fracture; **AND**
 - Patient must have a diagnosis of postmenopausal osteoporosis; **AND**
 - Patient has had a T-score at or below –2.5 at the femoral neck, spine, total hip, and/or 33% radius (wrist); **AND**
 - Patient has failed or is intolerant to other available osteoporosis therapy; **OR**
 - Male Osteoporosis (MO)
 - Patient must be 18 years of age or older; **AND**
 - Patient is at very high risk for fracture; **AND**
 - Patient must have a diagnosis of male osteoporosis; **AND**

- Patient has had a T-score at or below –2.5 at the femoral neck, spine, total hip, and/or 33% radius (wrist); **AND**
- Patient has failed or is intolerant to other available osteoporosis therapy; **OR**
- Glucocorticoid-Induced Osteoporosis (GIO)
 - Patient must be 18 years of age or older; **AND**
 - Patient is at very high risk for fracture; **AND**
 - Patient has had a T-score at or below –2.5 at the femoral neck, spine, total hip, and/or 33% radius (wrist); **AND**
 - Patient must have a diagnosis of glucocorticoid-induced osteoporosis; **AND**
 - Patient is currently receiving or will be initiating glucocorticoid therapy; **AND**
 - Patient has failed or is intolerant to other available osteoporosis therapy; **OR**
- Therapeutic Management of Aromatase Inhibitor–Induced Bone Loss in Women Undergoing Adjuvant Therapy for Breast Cancer
 - Patient must be 18 years of age or older; **AND**
 - Must be prescribed by or in consultation with an oncologist; **AND**
 - Patient must have a diagnosis of breast cancer; **AND**
 - Patient is receiving aromatase inhibitor therapy; **AND**
 - Patient has failed or is intolerant to other available osteoporosis therapy; **OR**
- Therapeutic Management of Androgen Deprivation Therapy–Induced Bone Loss in Men Undergoing Treatment for Prostate Cancer
 - Patient must be 18 years of age or older; **AND**
 - Must be prescribed by or in consultation with an oncologist; **AND**
 - Patient must have a diagnosis of non-metastatic prostate cancer; **AND**
 - Patient is receiving androgen deprivation therapy; **AND**
 - Patient has failed or is intolerant to other available osteoporosis therapy

Xgeva and biosimilars

- Patient must be 18 years of age or older; **AND**
- Must be prescribed by or in consultation with a provider; **AND**
- Patient is not taking Prolia or a Prolia biosimilar while taking this medication; **AND**
- Patient must have a diagnosis of the following:
 - Giant Cell Tumor of the Bone
 - Patient must be 18 years of age or older; **AND**
 - Patient must be a skeletally mature adolescent as defined by having at least 1 mature long bone (e.g., closed epiphyseal growth plate of the humerus); **AND**
 - Patient disease is unresectable **OR** surgical resection is likely to result in severe morbidity; **OR**
 - Prevention of Skeletal-Related Events
 - Patient must be 18 years of age or older; **AND**
 - Patient must have a presence of bone metastases from solid tumors **OR** diagnosis of multiple myeloma; **AND**
 - Patient with prostate cancer must have castration-resistant prostate cancer; **AND**
 - Must be prescribed by, or in consultation with, a hematologist or an oncologist; **OR**

- Hypercalcemia of Malignancy
 - Patient must be 18 years of age or older; **AND**
 - Patient has a current malignancy **AND**
 - Patient has demonstrated refractory (within the past 30 days) **OR** contraindication (including renal insufficiency) **OR** intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); **AND**
 - Must be prescribed by, or in consultation with, a hematologist or an oncologist

Renewal Criteria:

Coverage may be renewed if all the following are met:

- Patient continues to meet the Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity

Length of Authorization:

1 year

Applicable Procedure Codes

Code	Description
J0897	Injection, denosumab, 1 mg; 1 mg = 1 billable unit
Q5136	Injection, denosumab-bbdz (Jubbonti/Wyost), biosimilar, 1mg
Q5157	Injection, denosumab-bmwo (Stoboclo/Osenvelt), biosimilar, 1 mg; 1 billable unit = 1 mg
Q5158	Injection, denosumab-bnht (Bomynta/Conexxence), biosimilar, 1 mg; 1 billable unit = 1 mg
Q5159	Injection, denosumab-dssb (Ospomyv), biosimilar, 1 mg; 1 billable unit = 1 mg
Q5161	Injection, denosumab-kyqq (Aukelso/Bosaya), biosimilar, 1 mg
Q5162	Injection, denosumab-nxxp (Bildyos/Bilprevda), biosimilar, 1 mg
Q5165	Injection, denosumab-mobz (Oziltus/Xbryk), biosimilar, 1 mg
Q5166	Injection, denosumab-desu (Osvyrti/Jubereq), biosimilar, 1 mg
Q5167	Injection, denosumab-qbde (Enoby/Xtrenbo), biosimilar, 1 mg
Q5171	Injection, denosumab-mobz (Boncresa), biosimilar, 1 mg
J3590	Unclassified drugs or biologicals (Ponlimsi)

Applicable NDCs

Code	Description
55513-0710-XX	Prolia 60 mg/1 mL single-use prefilled syringe
55513-0730-XX	Xgeva 120 mg/1.7 mL single-use vial
61314-0240-XX	Jubbonti 60mg/mL single-dose prefilled syringe
61314-0228-XX	Wyost 120mg/1.7 mL single-dose vial
72606-0037-XX	Stoboclo 60mg/1mL single dose prefilled syringe
72606-0038-XX	Osenvelt 120mg/1.7mL single dose vial
65219-0668-XX	Conexxence 60 mg/1 mL single-dose prefilled syringe

Code	Description
65219-0670-XX	Bomyntra 120 mg/1.7 mL single-dose vial
65219-0672-XX	Bomyntra 120 mg/1.7 mL single-dose prefilled syringe
71202-0012-XX	Ospomyv 60 mg/1 mL single-dose prefilled syringe:
83257-0029-XX	Bosaya 60 mg/1 mL single-dose prefilled syringe
83257-0030-XX	Aukelso 120 mg/1.7 mL single-dose vial
78206-0193-XX	Bildyos 60 mg/mL solution prefilled syringe
78206-0194-XX	Bildyos 60 mg/mL solution in a single dose vial
78206-0195-XX	Bilprevda 120 mg/1.7mL solution
70121-2701-XX	Oziltus 120 mg/1.7mL solution
69448-0021-XX	Osvyrti 60 mg/1 mL single-dose prefilled syringe
69448-0022-XX	Jubereq 120 mg/1.7 mL single-dose vial
00143-9165-XX	Enoby 60 mg/1 mL single-dose prefilled syringe
00143-9166-XX	Xtrenbo 120 mg/1.7 mL single-dose vial
70121-2702-XX	Boncresa 60 mg/1 mL single-dose prefilled syringe
51759-0309-XX	Ponlimsi 60 mg/1 mL single-dose prefilled syringe

ICD-10 Diagnoses: Prolia, Jubbonti, Ospomyv, Stoboclo, Connexence, Bildyos, Ponlimsi, Osvyrti, Bosaya

Code	Description
C50.011- C50.929	Malignant neoplasms of breast
C61	Malignant neoplasm of prostate
D05.10	Intraductal carcinoma in situ of unspecified breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
M80.00XA- M80.08XS	Age-related osteoporosis with current pathological fracture
M80.8B2A-M80.8B2S	Other osteoporosis with current pathological fracture
M80.8B9AM80.8B9S	Osteoporosis with current pathological fracture
M81.0	Age-related osteoporosis without current pathological fracture
M81.6	Localized osteoporosis [Lequesne]
M81.8	Other osteoporosis without current pathological fracture
M85.80	Other specified disorders of bone density and structure, unspecified site
M85.851	Other specified disorders of bone density and structure, right thigh
M85.852	Other specified disorders of bone density and structure, left thigh

Code	Description
M85.859	Other specified disorders of bone density and structure, unspecified thigh
M85.88	Other specified disorders of bone density and structure, other site
M85.89	Other specified disorders of bone density and structure, multiple sites
T38.OX5A	Adverse effect of glucocorticoids and synthetic analogues, initial encounter
T38.OX5S	Adverse effect of glucocorticoids and synthetic analogues, sequela
Z79.810	Long term (current) use of selective estrogen receptor modulators (SERMs)
Z85.3	Personal history of malignant neoplasm of breast

ICD-10 Diagnoses: Xgeva, Wyost, Osenvelt, Bomynta, Bilprevda, Jubereq, Aukelso

Code	Description
C00-C14	Malignant neoplasms of lip, oral cavity and pharynx
C15-C26	Malignant neoplasms of digestive organs
C30-C39	Malignant neoplasms of respiratory and intrathoracic organs
C40-C41	Malignant neoplasms of bone and articular cartilage
C43-C44	Melanoma and other malignant neoplasms of skin
C45-C49	Malignant neoplasms of mesothelial and soft tissue
C50.011- C50.929	Malignant neoplasms of breast
C51-C58	Malignant neoplasms of female genital organs
C60-C63	Malignant neoplasms of male genital organs
C64-C68	Malignant neoplasms of urinary tract
C69-C72	Malignant neoplasms of eye, brain and other parts of central nervous system
C73-C75	Malignant neoplasms of thyroid and other endocrine glands
C7A.00- C7A.8	Malignant neuroendocrine tumors
C7B.00- C7B.8	Secondary neuroendocrine tumors
C76-C80	Malignant neoplasms of ill-defined, other secondary and unspecified sites
C81	Hodgkin lymphoma
C82	Follicular lymphoma
C83	Non-follicular lymphoma
C84	Mature T/NK-cell lymphomas
C85	Other specified and unspecified types of non-Hodgkin lymphoma
C86	Other specified types of T/NK-cell lymphoma
C88	Malignant immunoproliferative diseases and certain other B-cell lymphomas
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma, in relapse
C90.10	Plasma cell leukemia not having reached remission
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse

Code	Description
C90.20	Extramedullary plasmacytoma not having reached remission
C90.21	Extramedullary plasmacytoma in remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.31	Solitary plasmacytoma in remission
C90.32	Solitary plasmacytoma in relapse
C94.30	Mast cell leukemia not having achieved remission
C94.31	Mast cell leukemia, in remission
C94.32	Mast cell leukemia, in relapse
C96.20	Malignant mast cell neoplasm, unspecified
C96.21	Aggressive systemic mastocytosis
C96.22	Mast cell sarcoma
C96.29	Other malignant mast cell neoplasm
D00-D09	In situ neoplasms
D10-D36	Benign neoplasms, except benign neuroendocrine tumors
D3A.00- D3A.8	Benign neuroendocrine tumors
D37-D44	Neoplasm of uncertain behavior of oral cavity and digestive organs - Neoplasm of uncertain behavior of endocrine glands
D47.02	Systemic mastocytosis
D48	Neoplasm of uncertain behavior of other and unspecified sites
D49.0- D49.9	Neoplasms of unspecified behavior
E83.52	Hypercalcemia
Z85	Personal history of malignant neoplasm
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.