Denosumab:
Prolia®; Xgeva®
(Subcutaneous)

Document Number: MODA-0098

Last Review Date: 04/04/2022

Date of Origin: 11/28/2011

Dates Reviewed: 12/2011, 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 06/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 01/2017, 05/2017, 08/2017, 11/2017, 02/2018, 05/2018, 06/2018, 04/2019, 04/2020, 04/2021, 04/2022

I. Length of Authorization

Coverage will be provided for 12 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Prolia 60 mg/1 mL single-dose prefilled syringe: 1 syringe every 6 months
- Xgeva 120 mg/1.7 mL single-dose vial:
  - Load: 4 vials for one 28-day cycle
  - Maintenance: 1 vial monthly

B. Max Units (per dose and over time) [HCPCS Unit]:

Prolia	All indications: • 60 billable units every 6 months
Xgeva	*Giant Cell Tumor of Bone & Hypercalcemia of Malignancy* – Loading Dose: • 120 billable units on days 1, 8, 15, and 29 – Maintenance: • 120 billable units every 4 weeks
	Bone metastases from solid tumors, Multiple Myeloma, & Systemic Mastocytosis: • 120 billable units every 4 weeks

III. Initial Approval Criteria

Site of care specialty infusion program requirements are met (refer to Moda Site of Care Policy).

Prolia

Universal Criteria [1,8,29]

- Patient must be supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily; **AND**
- Patient must not have hypocalcemia; **AND**

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient must be at a high risk for fracture**; **AND**
- Pregnancy ruled out prior to starting therapy in women of child-bearing potential; **AND**

Osteoporosis in Men and Women † [1,8,26,27,29]

- Women only: Patient must be post-menopausal; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
    - Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score ≤-2.5 and/or forearm DXA at the 33% (one-third) radius site; **OR**
    - T-score ≤-1 or low bone mass and a history of fragility fracture to the hip or spine; **OR**
    - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; **OR**
- Patient has a documented contraindication* or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid

Glucocorticoid-Induced Osteoporosis † [1,19]

- Patient will be initiating or is continuing systemic glucocorticoid therapy at a daily dosage equivalent to ≥ 7.5 mg of prednisone and is expected to remain on glucocorticoid therapy for at least 6 months; **AND**
    - Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; **OR**
    - Patient has a documented contraindication* or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid

Osteoporosis treatment and prevention in prostate cancer patients † [1,3,20]

- Documented Hip DXA (femoral neck or total hip) or lumbar spine T-score ≤-1 (or patient meets the diagnostic criteria for osteoporosis above); **AND**
- Patient must be receiving androgen deprivation therapy for non-metastatic prostate cancer

Osteoporosis treatment and prevention in breast cancer patients † [1,3,21]

- Patient must be receiving adjuvant aromatase inhibitor therapy for breast cancer

±Ineffective response is defined as one or more of the following: [8,29,31]
– Decrease in T-score in comparison with baseline T-score from DXA scan – Patient has a new fracture while on bisphosphonate therapy
****High risk for fractures include, but are not limited to, one or more of the following: [8,29]**
– History of an osteoporotic fracture as an adult – Parental history of hip fracture – Low BMI – Rheumatoid arthritis – Alcohol intake (3 or more drinks per day) – Current smoking – History of oral glucocorticoids ≥5 mg/d of prednisone (or equivalent) for >3 months (ever)
***Examples of contraindications to oral bisphosphonate therapy include the following: [30]**
– Documented inability to sit or stand upright for at least 30 minutes – Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia – Surgical anastomoses are present in the GI tract after certain types of bariatric surgery (e.g., Roux-en-Y gastric bypass).
***Examples of contraindications to injectable bisphosphonate therapy include the following: [30]**
– Documented pre-existing hypocalcemia and disturbances of mineral metabolism – Documented pre-existing renal insufficiency defined as creatinine clearance < 35 mL/min

Xgeva

Universal Criteria [1,8,32]

- Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia; **AND**
- Patient must not have hypocalcemia; **AND**

Coverage is provided in the following conditions:

Prevention of skeletal-related events in patients with multiple myeloma OR bone metastases from solid tumors † [2,3,14-16,22,25]

- Patient is at least 18 years of age; **AND**
  - Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of Zoledronic Acid; **OR**
  - Patient has metastatic breast cancer, metastatic castration-resistant prostate cancer, or metastatic lung cancer (both SCLC and NSCLC)

Giant Cell Tumor of the Bone † Φ [2,3,5,23,24]

- Patient must be an adult or at least 12 years of age and skeletally mature; **AND**
  - Disease is unresectable or surgical resection is likely to result in severe morbidity; **OR**
  - Disease is localized, recurrent, or metastatic ‡; **AND**
    - Used as a single agent; **OR**
    - Used in combination with interferon alpha, serial embolization, or radiation therapy

Hypercalcemia of malignancy † Φ [2,3,9]

- Patient is at least 18 years of age; **AND**
- Patient must have a diagnosis of cancer (malignancy); **AND**
  - Patient must have a diagnosis of refractory hypercalcemia of malignancy defined as an albumin-corrected calcium of >12.5 mg/dL (3.1 mmol/L) despite treatment with a minimum seven (7) day trial on previous therapy with intravenous (IV) bisphosphonates such as ibandronate or zoledronic acid; **OR**
  - Patient has a documented contraindication* or intolerance to intravenous (IV) bisphosphonates such as ibandronate or zoledronic acid

Systemic Mastocytosis ‡ [3,28]

- Patient has osteopenia or osteoporosis and coexisting bone pain; **AND**
- Used as second line therapy; **AND**
  - Patient is not responding to bisphosphonate therapy; **OR**
  - Patient is not a candidate for bisphosphonate therapy due to renal insufficiency

*Examples of contraindications to injectable bisphosphonate therapy include the following: [30]
– Documented pre-existing hypocalcemia and disturbances of mineral metabolism – Documented pre-existing renal insufficiency defined as creatinine clearance < 35 mL/min

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,2]

Coverage can be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe symptomatic hypocalcemia, osteonecrosis of the jaw, atypical femoral fractures, dermatological adverse reactions, severe infection, severe hypersensitivity/anaphylaxis, musculoskeletal pain, etc.; **AND**

Prolia [1,3,26,27,31]

- Disease response as indicated by one or more of the following:
  - Absence of fractures
  - Increase in bone mineral density compared to pretreatment baseline; **AND**

Osteoporosis in Men and Women ONLY:

  - After 5 years of treatment, patient will have a repeat DXA performed; **AND**
    - Patients with low-to moderate risk disease will have therapy changed to an oral or IV bisphosphonate unless there is a contraindication or intolerance to both dosage forms

Xgeva [2,3,24]

- Disease response as indicated by the following:
  - Multiple Myeloma OR Bone metastases from solid tumors: absence/delay in skeletal-related events (e.g., pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression)
  - Giant Cell Tumor of the Bone: stabilization of disease or decrease in size of tumor or spread of tumor
  - Hypercalcemia of Malignancy: corrected serum calcium ≤ 11.5 mg/dL (2.9 mmol/L)
  - Systemic Mastocytosis: improvement or resolution of bone pain as compared to pretreatment baseline

V. Dosage/Administration [1,2]

Prolia

Indication	Dose
All indications	60 mg subcutaneously by a health care provider every 6 months

Xgeva

Indication	Dose
Bone metastases from solid tumors, Multiple Myeloma, & Systemic Mastocytosis	120 mg subcutaneously by a health care provider every 4 weeks
Giant Cell Tumor of Bone & Hypercalcemia of Malignancy	120 mg subcutaneously by a health care provider every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy.

VI. Billing Code/Availability Information

HCPCS Code:

- J0897 – Injection, denosumab, 1 mg; 1 mg = 1 billable unit

NDC:

- Prolia 60 mg/1 mL single-dose prefilled syringe: 55513-0710-XX
- Xgeva 120 mg/1.7 mL single-dose vial: 55513-0730-XX

VII. References

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Appendix 1 – Covered Diagnosis Codes

Prolia

ICD-10	ICD-10 Description
C50.011-C50.929	Malignant neoplasms of breast
C61	Malignant neoplasm of prostate
M80.00XA-M80.08XS	Age-related osteoporosis with current pathological fracture
M80.80XA-M80.88XS	Other 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
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
T38.0X5A	Adverse effect of glucocorticoids and synthetic analogues, initial encounter
T38.0X5S	Adverse effect of glucocorticoids and synthetic analogues, sequela

Xgeva

ICD-10	ICD-10 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
C90.20	Extramedullary plasmacytoma not having reached remission
C90.21	Extramedullary plasmacytoma in remission

ICD-10	ICD-10 Description
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	Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue
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
D48.0	Neoplasm of uncertain behavior of bone and articular cartilage
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
Z85.528	Personal history of other malignant neoplasm of kidney

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Articles may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/Article):

Prolia and Xgeva

Jurisdiction(s): 6, K	**NCD/LCD Document (s):** A52399
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52399&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): N	**NCD/LCD Document (s):** A57603
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57603&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC