

Denosumab:
Prolia®; Xgeva®
(Subcutaneous)

Document Number: IC-0098

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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]:

| | |
|----------------------|--|
| <u>Prolia</u> | <u>All indications:</u> <ul style="list-style-type: none"> • 60 billable units every 6 months |
| <u>Xgeva</u> | <u>Giant Cell Tumor of Bone & Hypercalcemia of Malignancy</u> <ul style="list-style-type: none"> - <u>Loading Dose:</u> <ul style="list-style-type: none"> • 120 billable units on days 1, 8, 15, and 29 - <u>Maintenance:</u> <ul style="list-style-type: none"> • 120 billable units every 4 weeks |
| | <u>Bone metastases from solid tumors, Multiple Myeloma, & Systemic Mastocytosis:</u> <ul style="list-style-type: none"> • 120 billable units every 4 weeks |

III. Initial Approval Criteria

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 $\geq 20\%$ or hip fracture $\geq 3\%$; **AND**
- Documented treatment failure or ineffective response \pm 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 \pm 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 |
| <ul style="list-style-type: none"> – 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 |
| <ul style="list-style-type: none"> – 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 |
| <ul style="list-style-type: none"> – 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 |
| <ul style="list-style-type: none"> – 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**

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- 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 |

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| ICD-10 | ICD-10 Description |
|------------------|---|
| 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 |
| 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 |

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| ICD-10 | ICD-10 Description |
|------------------|---|
| 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%2CMD%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 |

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