

Denosumab: **Prolia®; Xgeva®** (Subcutaneous)

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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) [HCP/CS 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 ^{1,29,33}

- 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 † 1,26,27,29,33

- 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**
- Patient has one of the following:
 - 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: 29,31,33
<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: 29,33
<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 esophageal disorders such as achalasia, esophageal stricture, esophageal varices, or Barrett's esophagus – 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 2,32,33

- 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

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- 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 serial embolization and/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:

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- 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 administered subcutaneously by a health care provider every 6 months

Xgeva

Indication	Dose
Bone metastases from solid tumors, Multiple Myeloma, & Systemic Mastocytosis	120 mg administered subcutaneously by a health care provider every 4 weeks
Giant Cell Tumor of Bone & Hypercalcemia of Malignancy	120 mg administered 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

1. Prolia [package insert]. Thousand Oaks, CA; Amgen, Inc.; January 2023. Accessed March 2023.
2. Xgeva [package insert]. Thousand Oaks, CA; Amgen, Inc.; June 2020. Accessed March 2023.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Denosumab. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2023.
4. Branstetter DG, Nelson SD, Manivel JC, et al. Denosumab induces tumor reduction and bone formation in patients with giant-cell tumor of bone. Clin Cancer Res. 2012 Aug 15;18(16):4415-24.
5. Thomas D, Henshaw R, Skubitz K, et al. Denosumab in patients with giant-cell tumor of bone: an open-label, phase 2 study. Lancet Oncol. 2010 Mar;11(3):275-80.
6. WHO Scientific Group on the Prevention and Management of Osteoporosis. Prevention and management of osteoporosis: report of a WHO scientific group. (WHO technical report series; 921). Geneva, Switzerland: WHO; 2000.
7. Kanis JA on behalf of the World Health Organization Scientific Group (2007). Assessment of osteoporosis at the primary health care level. Technical Report. World Health Organization Collaborating Center for Metabolic Bone Diseases. University of Sheffield, UK; 2007.
8. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014.
9. Hu MI, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. J Clin Endocrinol Metab. 2014 Sep;99(9):3144-52. doi: 10.1210/jc.2014-1001. Epub 2014 Jun 10.
10. Camacho PM, Petak SM, Binkley N, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY CLINICAL PRACTICE GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS - 2016. Endocr Pract. 2016 Sep 2; 22(Suppl 4):1-42.
11. Gnant M, Pfeiler G, Dubsy PC, et al. Adjuvant denosumab in breast cancer (ABC SG-18): a multicentre, randomised, double-blind, placebo-controlled trial. Lancet. 2015 Aug 1;386(9992):433-43.

12. Qaseem A, Forciea MA, McLean RM, Denberg TD; Clinical Guidelines Committee of the American College of Physicians. Treatment of Low Bone Density or Osteoporosis to Prevent Fractures in Men and Women: A Clinical Practice Guideline Update from the American College of Physicians. *Ann Intern Med.* 2017 May 9. doi: 10.7326/M15-1361.
13. Jeremiah MP, Unwin BK, Greenawald MH, et al. Diagnosis and Management of Osteoporosis. *Am Fam Physician.* 2015 Aug 15;92(4):261-8.
14. Henry DH, Costa L, Goldwasser F, et al. Randomized, Double-Blind Study of Denosumab Versus Zoledronic Acid in the Treatment of Bone Metastases in Patients With Advanced Cancer (Excluding Breast and Prostate Cancer) or Multiple Myeloma. *Journal of Clinical Oncology* 2011 29:9, 1125-1132. 2011 Mar 20.
15. Stopeck AT, Lipton A, Body JJ, et al. Denosumab compared with zoledronic acid for the treatment of bone metastases in patients with advanced breast cancer: a randomized, double-blind study. *J Clin Oncol.* 2010 Dec 10;28(35):5132-9.
16. Fizazi K, Carducci M, Smith M, et al. Denosumab versus zoledronic acid for treatment of bone metastases in men with castration-resistant prostate cancer: a randomised, double-blind study. *Lancet.* 2011 Mar 5;377(9768):813-22.
17. Cummings SR, San Martin J, McClung MR, et al. Denosumab for Prevention of Fractures in Postmenopausal Women With Osteoporosis. *N Engl J Med,* 361 (8), 756-65; 2009 Aug 20. PMID: 19671655. DOI: 10.1056/NEJMoa0809493.
18. Orwoll E, Teglbjaerg CS, Langdahl BL, et al. A Randomized, Placebo-Controlled Study of the Effects of Denosumab for the Treatment of Men With Low Bone Mineral Density. *J Clin Endocrinol Metab,* 97 (9), 3161-9; Sept 2012. PMID: 22723310. DOI: 10.1210/jc.2012-1569.
19. Saag KG, Wagman RB, Geusens P, et al. Denosumab Versus Risedronate in Glucocorticoid-Induced Osteoporosis: A Multicentre, Randomised, Double-Blind, Active-Controlled, Double-Dummy, Non-Inferiority Study. *Lancet Diabetes Endocrinol,* 6 (6), 445-454; Jun 2018. PMID: 29631782. DOI: 10.1016/S2213-8587(18)30075-5.
20. Smith MR, Egerdie B, Hernandez Toriz N, et al. Denosumab in Men Receiving Androgen-Deprivation Therapy for Prostate Cancer. *N Engl J Med.* 2009 Aug 20; 361(8): 745-755.
21. Ellis GK, Bone HG, Chlebowski R, et al. Randomized Trial of Denosumab in Patients Receiving Adjuvant Aromatase Inhibitors for Nonmetastatic Breast Cancer. *J Clin Oncol,* 26 (30), 4875-82; 2008 Oct 20. PMID: 18725648. DOI: 10.1200/JCO.2008.16.3832.
22. Raje N, Terpos E, Willenbacher W, et al. Denosumab Versus Zoledronic Acid in Bone Disease Treatment of Newly Diagnosed Multiple Myeloma: An International, Double-Blind, Double-Dummy, Randomised, Controlled, Phase 3 Study. *Lancet Oncol,* 19 (3), 370-381; Mar 2018. PMID: 29429912. DOI: 10.1016/S1470-2045(18)30072-X.
23. Chawla S, Henshaw R, Seeger L, et al. Safety and Efficacy of Denosumab for Adults and Skeletally Mature Adolescents With Giant Cell Tumour of Bone: Interim Analysis of an Open-Label, Parallel-Group, Phase 2 Study. *Lancet Oncol,* 14 (9), 901-8; Aug 2013. PMID: 23867211. DOI: 10.1016/S1470-2045(13)70277-8.

24. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bone Cancer. Version 2.2023. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2023.
25. Scagliotti GV, Hirsh V, Siena S, et al. Overall Survival Improvement in Patients With Lung Cancer and Bone Metastases Treated With Denosumab Versus Zoledronic Acid: Subgroup Analysis From a Randomized Phase 3 Study. *J Thorac Oncol*, 7 (12), 1823-1829; Dec 2012. PMID: 23154554. DOI: 10.1097/JTO.0b013e31826aec2b.
26. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society* Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*, Volume 104, Issue 5, May 2019, Pages 1595–1622, <https://doi.org/10.1210/jc.2019-00221>. Published: 25 March 2019.
27. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update. *J Clin Endocrinol Metab*. 2020 Mar 1;105(3):dgaa048. Doi: 10.1210/clinem/dgaa048.
28. Orsolini G, Gavioli I, Tripi G, et al. Denosumab for the Treatment of Mastocytosis-Related Osteoporosis: A Case Series. *Calcif Tissue Int*. 2017 Jun;100(6):595-598. doi: 10.1007/s00223-017-0241-z.
29. Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society. *Menopause*. 2021 Sep 1;28(9):973-997. Doi: 10.1097/GME.0000000000001831.
30. Rosen HN. (2022). Bisphosphonate therapy for the treatment of osteoporosis. In Rosen CJ, Schumacher KE (Eds.), *UptoDate*. Last updated: July 21, 2022. Accessed March 7, 2023. Available from https://www.uptodate.com/contents/bisphosphonate-therapy-for-the-treatment-of-osteoporosis?sectionName=Contraindications%20to%20bisphosphonates&search=postmenopausal%20osteoporosis&topicRef=2064&anchor=H3422893804&source=see_link#H3422893804
31. Camacho PM, Petak SM, Binkley N, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS/AMERICAN COLLEGE OF ENDOCRINOLOGY CLINICAL PRACTICE GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS-2020 UPDATE. *Endocr Pract*. 2020 May;26(Suppl 1):1-46. doi: 10.4158/GL-2020-0524SUPPL.
32. Jackson RD, LaCroix AZ, Gass M, Women’s Health Initiative Investigators. Calcium plus vitamin D supplementation and the risk of fractures. *N Engl J Med*. 2006; 354(7):669–683.
33. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician’s guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2022 Oct;33(10):2049-2102. Doi: 10.1007/s00198-021-05900-y. Epub 2022 Apr 28.

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34. Qaseem A, Hicks LA, Etcheandia-Ikobaltzeta I, et al; Clinical Guidelines Committee of the American College of Physicians. Pharmacologic Treatment of Primary Osteoporosis or Low Bone Mass to Prevent Fractures in Adults: A Living Clinical Guideline From the American College of Physicians. Ann Intern Med. [Epub 3 January 2023]. doi:10.7326/M22-1034.
35. National Government Services, Inc. Local Coverage Article: Billing and Coding: Denosumab (Prolia™, Xgeva™) (A52399). Centers for Medicare & Medicaid Services, Inc. Updated on 12/21/2022 with effective date 01/01/2021. Accessed March 2023.
36. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications (A57603). Centers for Medicare & Medicaid Services, Inc. Updated on 09/25/2020 with effective date 10/01/2020. Accessed March 2023.

Appendix 1 – Covered Diagnosis Codes

Prolia

ICD-10	ICD-10 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
M80.80XA- 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

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ICD-10	ICD-10 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
T38.0X5A	Adverse effect of glucocorticoids and synthetic analogues, initial encounter
T38.0X5S	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

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

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ICD-10	ICD-10 Description
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
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
Z85.3	Personal history of malignant neoplasm of breast

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ICD-10	ICD-10 Description
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

PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan (“PCHP”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaaajila gargaarsa afaanij, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສຍຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚኖሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ፡ 1.800.940.5049 (መለስማት ለተሳናቸው፡ 763.847.4013)፡

ဟ်သ့ဟ်သး- နမၤကတိၤ ကသီၤ ကျိၣ်အယိၤ, နမၤန့ၣ် ကျိၣ်အတၢ်မၤစၢၤလၢ တလၢၣ်ဘျဉ်လၢၣ်စၢၤ နီၣ်တမံၤဘၣ်သ့န့ၣ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំបាប់រឺអ៊ែក។ ចូរទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013), 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

PreferredOne Insurance Company Nondiscrimination Notice

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PIC:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

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- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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បំពេញ: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

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ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လိ။ ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

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