Prolia® is indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia® also reduced the incidence of vertebral fractures.

Prolia® is indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Item	Coding Information (HCPCS[1]/CPT[2]/ICD-10-CM[3])	Notes
Prolia®	J0897, SC injection, denosumab, 1 mg	Prolia® is supplied as a 60 mg dose; its NDC is 55513-0710-01
	96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular; **OR** 96401, chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic	The Medicare Claims Processing Manual (CPM) and the American Medical Association (AMA) indicate that chemotherapy codes may be appropriate in the treatment of noncancer diagnosis or to substances, such as certain monoclonal antibody agents, and other biologic response modifiers. However, third-party payers (or local carriers in the case of Medicare) make the determination for which specific codes are appropriate for billing Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of Prolia®
Administration	Relevant Evaluation and Management (E&M) code*,†	See payer guidelines
Diagnosis/ Condition	Appropriate ICD-10-CM code(s) for patient condition Sequencing of codes may vary based on patient's condition and payer's policy	Coding requirements for men receiving androgen deprivation therapy for nonmetastatic prostate cancer or women receiving adjuvant aromatase inhibitor therapy for breast cancer will vary from payer to payer but may include the following factors as appropriate: **Cancer Diagnosis:** Example – C61 Malignant neoplasm of prostate **Use of Androgen Deprivation or Aromatase Inhibitor Therapy:** Example – Z79.818 Long term (current) use of other agents affecting estrogen receptors and estrogen levels‡ **OR** Z79.899 Other long term (current) drug therapy **Other Risk Factors for Fracture:** Example – M85.9 Disorder of bone density and structure, unspecified§

* Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.

† Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when Modifier 25 is billed.

‡ Diagnosis code Z79.818 may be used for males receiving androgen deprivation therapy (eg, leuprolide acetate or goserelin acetate) for prostate cancer.

§ Code M85.9 may apply for osteopenia.

1. Centers for Medicare & Medicaid Services. 2015 Alpha-Numeric HCPCS File. Available at: http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2015-Alpha-Numeric-HCPCS-File-%C2%A0.html. Accessed May 29, 2015.
2. American Medical Association. Current Procedural Terminology (CPT®) copyright 2014 American Medical Association. 2015. All Rights Reserved.
3. Centers for Medicare & Medicaid Services. 2015 ICD-10-CM Tabular List of Diseases and Injuries. Available at: http://www.cdc.gov/nchs/icd/icd10cm.htm#icd2016. Accessed July 23, 2015.

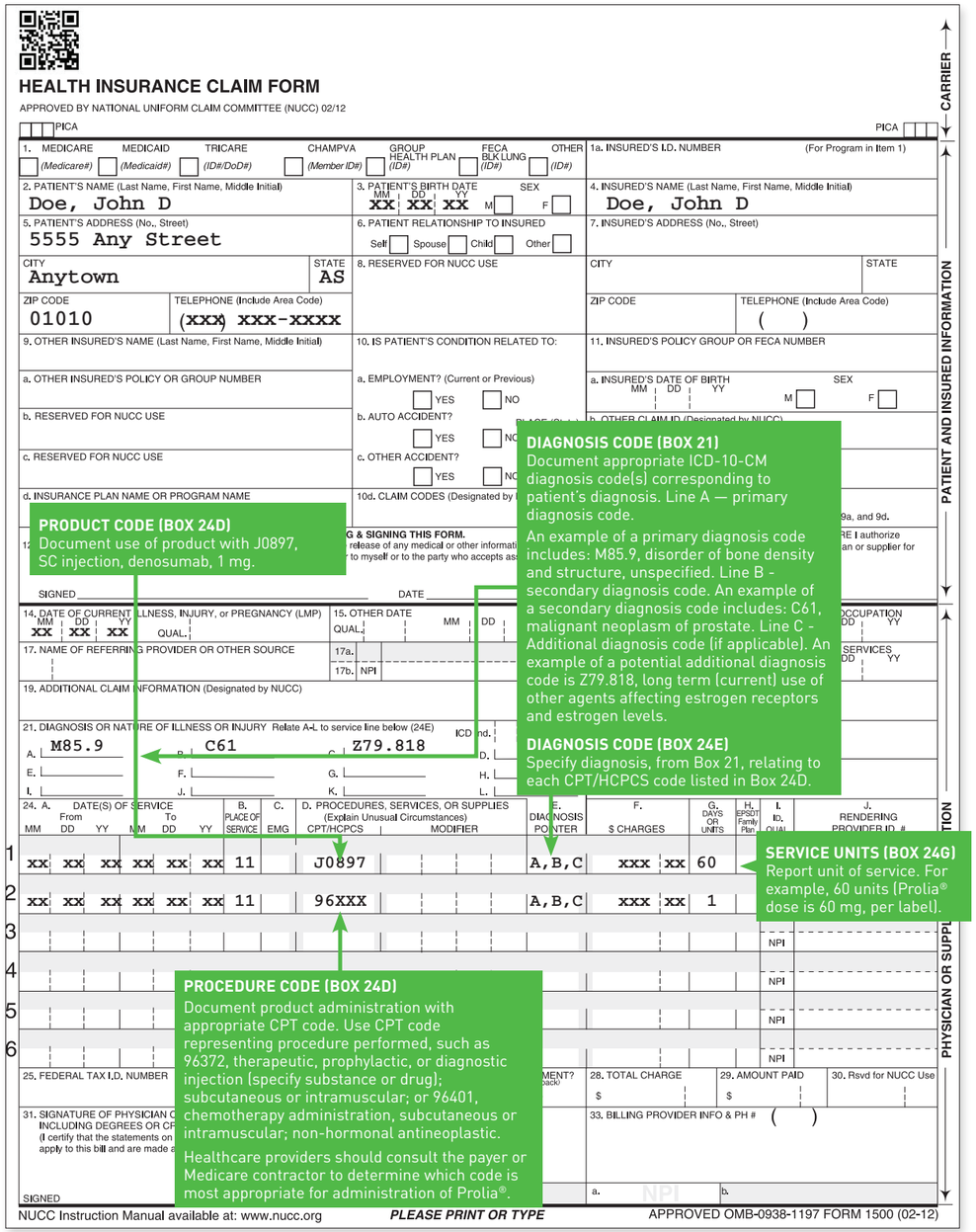
Contact Amgen Assist® at 1-888-4ASSIST for assistance.
www.AmgenAssistOnline.com

Please see Important Safety Information on pages 3 and 4.

prolia® (denosumab)
Subcutaneous injection.

The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John D

3. PATIENT'S BIRTH DATE MM DD YY: xx xx xx SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John D

5. PATIENT'S ADDRESS (No., Street): 5555 Any Street

6. PATIENT RELATIONSHIP TO INSURED: Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE: 01010 TELEPHONE (Include Area Code): (xxx) xxx-xxxx

ZIP CODE TELEPHONE (Include Area Code): ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

12. PATIENT'S AUTHORIZED PERSON'S SIGNATURE I authorize release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY: xx xx xx QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. M85.9 B. C61 C. Z79.818 D.

E. F. G. H.

I. J. K. L.

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY; B. PLACE OF SERVICE; C. EMG; D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER; E. DIAGNOSIS POINTER; F. $ CHARGES; G. DAYS OR UNITS; H. EPSDT Family Plan; I. ID. QUAL.; J. RENDERING PROVIDER ID. #

1	xx	xx	xx	xx	xx	xx	11		J0897			A,B,C	xxx	xx	60	
2	xx	xx	xx	xx	xx	xx	11		96XXX			A,B,C	xxx	xx	1	
3																NPI
4																NPI
5																NPI
6																NPI

25. FEDERAL TAX I.D. NUMBER

26. PATIENT'S ACCOUNT NO. (For govt. claims, see back)

27. ACCEPT ASSIGNMENT? (For govt. claims, see back)

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a

SIGNED

32. SERVICE FACILITY LOCATION INFO

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org **PLEASE PRINT OR TYPE** APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

PRODUCT CODE (BOX 24D)
Document use of product with J0897, SC injection, denosumab, 1 mg.

DIAGNOSIS CODE (BOX 21)
Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A — primary diagnosis code.

An example of a primary diagnosis code includes: M85.9, disorder of bone density and structure, unspecified. Line B - secondary diagnosis code. An example of a secondary diagnosis code includes: C61, malignant neoplasm of prostate. Line C - Additional diagnosis code (if applicable). An example of a potential additional diagnosis code is Z79.818, long term (current) use of other agents affecting estrogen receptors and estrogen levels.

DIAGNOSIS CODE (BOX 24E)
Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

SERVICE UNITS (BOX 24G)
Report unit of service. For example, 60 units (Prolia® dose is 60 mg, per label).

PROCEDURE CODE (BOX 24D)
Document product administration with appropriate CPT code. Use CPT code representing procedure performed, such as 96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular; or 96401, chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic.

Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of Prolia®.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Please see Important Safety Information on pages 3 and 4.

Contraindications

Prolia® is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating Prolia®. Prolia® is contraindicated in women who are pregnant and may cause fetal harm. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment with Prolia®. Prolia® is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling and urticaria.

Same Active Ingredient

Prolia® contains the same active ingredient (denosumab) found in XGEVA®. Patients receiving Prolia® should not receive XGEVA®.

Hypersensitivity

Clinically significant hypersensitivity including anaphylaxis has been reported with Prolia®.Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of Prolia®.

Hypocalcemia

Hypocalcemia may worsen with the use of Prolia®, especially in patients with severe renal impairment. In patients predisposed to hypocalcemia and disturbances of mineral metabolism, clinical monitoring of calcium and mineral levels is highly recommended within 14 days of Prolia® injection. Adequately supplement all patients with calcium and vitamin D.

Osteonecrosis of the Jaw (ONJ)

ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving Prolia®. An oral exam should be performed by the prescriber prior to initiation of Prolia®. A dental examination with appropriate preventive dentistry is recommended prior to treatment in patients with risk factors for ONJ such as invasive dental procedures, diagnosis of cancer, concomitant therapies (e.g. chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and co-morbid disorders. Good oral hygiene practices should be maintained during treatment with Prolia®. The risk of ONJ may increase with duration of exposure to Prolia®.

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of Prolia® should be considered based on individual benefit-risk assessment.

Atypical Femoral Fractures

Atypical low-energy, or low trauma fractures of the shaft have been reported in patients receiving Prolia®. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with anti-resorptive agents.

During Prolia® treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be evaluated to rule out an incomplete femur fracture. Interruption of Prolia® therapy should be considered, pending a risk/benefit assessment, on an individual basis.

Multiple Vertebral Fractures (MVF) Following Discontinuation of Prolia® Treatment

Following discontinuation of Prolia® treatment, fracture risk increases, including the risk of multiple vertebral fractures. New vertebral fractures occurred as early as 7 months (on average 19 months) after the last dose of Prolia®. Prior vertebral fracture was a predictor of multiple vertebral fractures after Prolia® discontinuation. Evaluate an individual's benefit/risk before initiating treatment with Prolia®. If Prolia® treatment is discontinued, consider transitioning to an alternative antiresorptive therapy.

Please see accompanying Prolia® full Prescribing Information, including Medication Guide.

prolia® (denosumab)

Subcutaneous injection.

Serious Infections

In a clinical trial (N = 7808) in women with postmenopausal osteoporosis, serious infections leading to hospitalization were reported more frequently in the Prolia® group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear, were more frequent in patients treated with Prolia®.

Endocarditis was also reported more frequently in Prolia® -treated patients. The incidence of opportunistic infections and the overall incidence of infections were similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis. Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Prolia®, prescribers should assess the need for continued Prolia® therapy.

Dermatologic Adverse Reactions

In the same clinical trial in women with postmenopausal osteoporosis, epidermal and dermal adverse events such as dermatitis, eczema and rashes occurred at a significantly higher rate with Prolia® compared to placebo. Most of these events were not specific to the injection site. Consider discontinuing Prolia® if severe symptoms develop.

Musculoskeletal Pain

Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking Prolia®. Consider discontinuing use if severe symptoms develop.

Suppression of Bone Turnover

In clinical trials in women with postmenopausal osteoporosis, Prolia® resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment are unknown. Monitor patients for consequences, including ONJ, atypical fractures, and delayed fracture healing.

Nursing Mothers

It is not known whether Prolia® is excreted into human milk. Measurable concentrations of denosumab were present in the maternal milk of cynomolgus monkeys up to 1 month after the last dose of denosumab (≤ 0.5% milk:serum ratio). Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Prolia®, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Adverse Reactions

The most common (per patient incidence ≥10%) adverse reactions reported with Prolia® in patients with bone loss receiving ADT for prostate cancer or adjuvant AI therapy for breast cancer are arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials. Additionally, in Prolia®-treated men with nonmetastatic prostate cancer receiving ADT, a greater incidence of cataracts was observed.

Please see accompanying Prolia® full Prescribing Information, including Medication Guide.

prolia® (denosumab)

Subcutaneous injection.