PROLIA®
CODING AND BILLING INFORMATIONAL RESOURCES USING THE CMS 1500 FORM
With ICD-10-CM Codes

AMGEN Assist®

Contact Amgen Assist® for assistance with specific payer requirements:
1-866-AMG-ASST (1-866-264-2778)

The information provided in this guide is of a general nature and for informational purposes only. Coding and coverage policies change periodically and often without warning. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient and/or procedure is always the responsibility of the provider or physician. The information provided in this guide should in no way be considered a guarantee of coverage or reimbursement for any product or service.

Please see Indications and Important Safety Information on the back and the accompanying Prolia® full Prescribing Information, including Medication Guide.

prolia® (denosumab) injection

PHYSICIAN OFFICE BILLING INFORMATION

Prolia® (denosumab) Coding Information[1]

HCPCS Code (J-Code) in Box 24D	• **J0897** (Injection, denosumab, 1 mg)
Number of Units in Box 24G	Use of a 60 mg prefilled syringe of Prolia® is reported as: • **60 units**

Administration and Professional Service Coding Information[2,*]

CPT Code in Box 24D	The following code may be available to report administration of Prolia®. Other codes may be appropriate on a payer-specific basis. It is the provider's responsibility to ensure that codes used are consistent with payer policy and reflect service performed under such codes: • **96372** (therapeutic, prophylactic or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular) • Relevant evaluation and management (E&M) code. Note when an E&M service is billed in addition to other professional services, the following modifier may be required to distinguish it as a separate service: -.25 (significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service)

Diagnosis Code Information*

ICD Code in Box 21	The following primary diagnosis codes may be appropriate to describe patients *without* current osteoporotic fracture treated with Prolia®: **ICD-10-CM Codes[3,†]** • **M81.0** (Age-related osteoporosis without current pathological fracture)‡ • **M81.8** (Other osteoporosis without current pathological fracture)‡

*** The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for Prolia®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.**

† See insert on the back for examples of ICD-10 codes for patients with current osteoporotic fracture.

‡ According to the ICD-10-CM Official Guidelines for Coding and Reporting, M81 code is for use for patients with osteoporosis who do not currently have a pathologic fracture due to the osteoporosis, even if they have had a fracture in the past. For patients with a history of osteoporosis fractures, status code Z87.310 (personal history of [healed] osteoporosis fracture) should follow the code from the M81 category.[4]

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COMPLETING THE CMS 1500 FOR PHYSICIAN OFFICES*

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 [X] (ID#)	FECA BLK LUNG (ID#)	OTHER (ID#)	1a. INSURED'S I.D. NUMBER (For Program in Item 1): XXX-XX-XXXX
2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, Jane J				3. PATIENT'S BIRTH DATE: 06 01 1930 SEX: M [ ] F [X]			4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, Jane J
5. PATIENT'S ADDRESS (No., Street): 1123 Main Street				6. PATIENT RELATIONSHIP TO INSURED: Self [ ] Spouse [ ] Child [ ] Other [ ]			7. INSURED'S ADDRESS (No., Street)
CITY: Hometown	STATE: MA			8. RESERVED FOR NUCC USE			CITY / STATE
ZIP CODE: 01234	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: 11111
a. OTHER INSURED'S POLICY OR GROUP NUMBER				a. EMPLOYMENT? (Current or Previous) YES [ ] NO [X]			a. INSURED'S DATE OF BIRTH: 06 01 1930 SEX: M [ ] F [X]
b. RESERVED FOR NUCC USE				b. AUTO ACCIDENT? YES [ ] NO [X] PLACE (State)			b. OTHER CLAIM ID (Designated by NUCC): ABC Employer
c. RESERVED FOR NUCC USE				c. OTHER ACCIDENT? YES [ ] NO [X]			c. INSURANCE PLAN NAME OR PROGRAM NAME
d. INSURANCE PLAN NAME OR PROGRAM NAME				10d. CLAIM CODES (Designated by NUCC)			d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES [ ] NO [X] *If yes*, complete items 9, 9a, and 9d.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE **I** authorize the 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. SIGNED _____

14. DATE OF CURRENT: ILLNESS (First symptom) OR INJURY (Accident) OR PREGNANCY (LMP) MM DD YY | 15. OTHER DATE QUAL. MM DD YY | 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE | 17a. | 17b. NPI | 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) | 20. OUTSIDE LAB? YES [ ] NO [ ] $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. | 22. RESUBMISSION CODE ORIGINAL REF. NO.

A. M81.0 B. C. D. E. F. G. H. I. J. K. L. | 23. PRIOR AUTHORIZATION NUMBER

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 01 23 14	01 23 14	11		J0897			XXX XX	60			
2 01 23 14	01 23 14	11		96372			XXX XX	1		NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER	SSN	EIN	26. PATIENT'S ACCOUNT NO.	27. ACCEPT ASSIGNMENT? (For govt. claims, see back)	28. TOTAL CHARGE	29. AMOUNT PAID	30. Rsvd for NUCC Use
11-1111111	[ ]	[X]		[X] YES [ ] NO	$ XXX XX	$	

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 part thereof.)	32. SERVICE FACILITY LOCATION INFORMATION	33. BILLING PROVIDER INFO & PH # ( )
SIGNED 11-22-16 DATE	a. XXXXXXXXX b.	John Smith MD 2 Doctors Blvd Hometown, MA 01234 a. XXXXXXXXX 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

Box 21. Diagnosis or Nature of Illness or Injury:
Indicate appropriate ICD diagnosis code as reflected in the patient's medical record. ICD-10 code example: M81.0 (Age-related osteoporosis without current pathological fracture)

Box 24G. Days or Units:
Indicate 60 units

Box 24D. Procedures, Services, or Supplies:
Indicate appropriate HCPCS and CPT codes. Example: J0897 (Injection, denosumab, 1 mg). 96372 (Therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)

Prolia® FDA-Approved Indications

Prolia® is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia® reduces the incidence of vertebral, nonvertebral and hip fractures.

Prolia® is indicated for treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Important Safety Information

- **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. 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.
- **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.
- **Adverse Reactions:** The most common adverse reactions (>5% and more common than placebo) in women with postmenopausal osteoporosis are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis.

  The most common adverse reactions (>5% and more common than placebo) in men with osteoporosis are back pain, arthralgia, and nasopharyngitis. Pancreatitis has been reported with Prolia®.

  In women with postmenopausal osteoporosis, the overall incidence of new malignancies was 4.3% in the placebo group and 4.8% in the Prolia® group. In men with osteoporosis, new malignancies were reported in no patients in the placebo group and 4 (3.3%) patients in the Prolia® group. A causal relationship to drug exposure has not been established. Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

Dosage and Administration

Prolia® is one 60 mg subcutaneous injection administered every 6 months in the upper arm, upper thigh, or abdomen by a healthcare professional. Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia®. Adequately supplement all patients with calcium and vitamin D. Multiple vertebral fractures have been reported following Prolia® discontinuation.

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

References: **1.** Centers for Medicare & Medicaid Services. 2016 Alpha-Numeric HCPCS File. Available at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2016-Alpha-Numeric-HCPCS-File.html. Accessed November 22, 2016. **2.** American Medical Association. 2017 Professional Edition, Current Procedural terminology (CPT). Copyright 2016 American Medical Association. 2017. All rights reserved. **3.** Centers for Disease Control and Prevention. International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM). 2017 ICD-10-CM tabular list of diseases and injuries. FY 2017 Full PDF. ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2017/. Accessed November 22, 2016. **4.** CMS. ICD-10-CM Official Guidelines for Coding and Reporting, FY 2017. Available at: http://www.cdc.gov/nchs/data/icd/10cmguidelines_2017_final.pdf. Accessed November 22, 2016.

AMGEN®

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AMGEN Assist®

prolia® (denosumab) injection

Examples of ICD-10-CM Codes Relevant for Prolia® Patients *WITH* Current Osteoporotic Fracture[3]

M80.0_ _ _ **Age-related osteoporosis with current pathological fracture [laterality] [anatomic site] [encounter type]***

Anatomic Site and Laterality	Encounter Type†					
	Initial encounter for fracture	Subsequent encounter for fracture with routine healing	Subsequent encounter for fracture with delayed healing	Subsequent encounter for fracture with nonunion	Subsequent encounter for fracture with malunion	Sequela
UNSPECIFIED SITE	M80.00XA	M80.00XD	M80.00XG	M80.00XK	M80.00XP	M80.00XS
SHOULDER						
Right	M80.011A	M80.011D	M80.011G	M80.011K	M80.011P	M80.011S
Left	M80.012A	M80.012D	M80.012G	M80.012K	M80.012P	M80.012S
Unspecified	M80.019A	M80.019D	M80.019G	M80.019K	M80.019P	M80.019S
HUMERUS						
Right	M80.021A	M80.021D	M80.021G	M80.021K	M80.021P	M80.021S
Left	M80.022A	M80.022D	M80.022G	M80.022K	M80.022P	M80.022S
Unspecified	M80.029A	M80.029D	M80.029G	M80.029K	M80.029P	M80.029S
FOREARM						
Right	M80.031A	M80.031D	M80.031G	M80.031K	M80.031P	M80.031S
Left	M80.032A	M80.032D	M80.032G	M80.032K	M80.032P	M80.032S
Unspecified	M80.039A	M80.039D	M80.039G	M80.039K	M80.039P	M80.039S
HAND						
Right	M80.041A	M80.041D	M80.041G	M80.041K	M80.041P	M80.041S
Left	M80.042A	M80.042D	M80.042G	M80.042K	M80.042P	M80.042S
Unspecified	M80.049A	M80.049D	M80.049G	M80.049K	M80.049P	M80.049S
FEMUR						
Right	M80.051A	M80.051D	M80.051G	M80.051K	M80.051P	M80.051S
Left	M80.052A	M80.052D	M80.052G	M80.052K	M80.052P	M80.052S
Unspecified	M80.059A	M80.059D	M80.059G	M80.059K	M80.059P	M80.059S
LOWER LEG						
Right	M80.061A	M80.061D	M80.061G	M80.061K	M80.061P	M80.061S
Left	M80.062A	M80.062D	M80.062G	M80.062K	M80.062P	M80.062S
Unspecified	M80.069A	M80.069D	M80.069G	M80.069K	M80.069P	M80.069S
ANKLE AND FOOT						
Right	M80.071A	M80.071D	M80.071G	M80.071K	M80.071P	M80.071S
Left	M80.072A	M80.072D	M80.072G	M80.072K	M80.072P	M80.072S
Unspecified	M80.079A	M80.079D	M80.079G	M80.079K	M80.079P	M80.079S
VERTEBRA(E)	M80.08XA	M80.08XD	M80.08XG	M80.08XK	M80.08XP	M80.08XS

See the back of the insert for hypothetical scenarios illustrating specificity of these M80.0_ _ _ ICD-10-CM codes. The diagnosis code examples above and the hypothetical scenarios on back of the insert are informational and should not be a substitute for an independent clinical decision. They are not intended to be directive or a guarantee of reimbursement. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient is always the responsibility of the provider or physician. Please contact your payer with any questions.

* According to the ICD-10-CM Official Guidelines for Coding and Reporting, M80.0 codes are for patients who have a current pathologic fracture at the time of an encounter. The codes under M80 identify the site of the fracture. A code from category M80, not a traumatic fracture code, should be used for any patient with known osteoporosis who suffers a fracture, even if the patient had a minor fall or trauma, if that fall or trauma would not usually break a normal, healthy bone.[4]

† According to the ICD-10-CM Official Guidelines for Coding and Reporting, seventh character A is for use as long as the patient is receiving active treatment for the fracture. Assignment of the seventh character is based on whether the patient is undergoing active treatment and not whether the provider is seeing the patient for the first time. Seventh character D is to be used for encounters after the patient has completed active treatment. The other seventh characters, listed under each subcategory in the Tabular List, are to be used for subsequent encounters for treatment of problems associated with healing, such as malunions, nonunions, and sequelae.[4]

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prolia® (denosumab) injection

Hypothetical Scenarios Illustrating Specificity of M80.0_ _ _ ICD-10-CM Codes

Clinical Diagnosis Details	Potential ICD-10-CM Code[3]
Postmenopausal osteoporosis	
Vertebral fractures	Age-related osteoporosis with current pathological fracture — **M80.08XA** — Fracture of vertebrae; Initial encounter for fracture
Encounter for evaluating and continuing treatment for the fractures	

Clinical Diagnosis Details	Potential ICD-10-CM Code[3]
Postmenopausal osteoporosis	
Fracture of left wrist	Age-related osteoporosis with current pathological fracture — **M80.032D** — Fracture of forearm; Left; Subsequent encounter for fracture with routine healing
Follow-up encounter for routine fracture management (after active treatment has been completed)	

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