PROLIA®
CODING AND BILLING INFORMATION GUIDE

For physician offices using the CMS 1500

For hospitals/institutions using the CMS 1450

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.

Prolia® is indicated for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

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.

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.

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 Important Safety Information on the back.

prolia® (denosumab) injection

Physician Office Billing Information – Osteoporosis

Prolia® (denosumab) Coding Information

Additional Claim Information in Box 19: (Electronic Form: Loop 2300, or 2400, NTE, 02)[1]	• **Prolia®** (denosumab) 60 mg
Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)[1]	• **HCPCS code (J-code): J0897** (injection, denosumab 1 mg)[2] • **NDC number: 55513-0710-01**[3]
Number of Units in Box 24G: (Electronic Form: Loop 2400, SV1, 04 [03 = UN])[1]	Use of a 60 mg prefilled syringe of Prolia® is reported as: • **60 units** The NDC number covers both injections[3]

Diagnosis Coding Information*

ICD-10-CM Code in Box 21: (Electronic Form: Loop 2300, HI, 01-2)[1]	The following primary diagnosis codes may be appropriate to describe patients ***with*** current osteoporotic fracture treated with Prolia®: • **M80.0** (Age-related osteoporosis with current pathological fracture)[4] Please see page 10 for additional examples of patients with current osteoporotic fracture.
	The following primary diagnosis codes may be appropriate for patients ***without*** current osteoporotic fracture treated with Prolia®: • **M81.0** (Age-related osteoporosis without current pathological fracture)[4,†] • **M81.8** (Other osteoporosis without current pathological fracture)[4,†]
	The following secondary diagnosis codes may be appropriate to describe patients for glucocorticoid-induced osteoporosis: • **T38.0X5** Adverse effect of glucocorticoids and synthetic analogues, sequela

Administration and Professional Service Coding Information*

Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)[1]	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)[5] • **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)

* 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.

† According to the ICD-10-CM Official Guidelines for Coding and Reporting, M81 code is for use with 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 osteoporotic fractures, status code Z87.310 (personal history of [healed] osteoporosis fracture) should follow the code from the M81 category.[6]

Please see Important Safety Information on the back.

Completing the CMS 1500 for Physician Offices – Osteoporosis

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#) [X] | 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 MM DD YY: xx xx xx — 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):

a. OTHER INSURED'S POLICY OR GROUP NUMBER:

b. RESERVED FOR NUCC USE:

c. RESERVED FOR NUCC USE:

d. INSURANCE PLAN NAME OR PROGRAM

10. IS PATIENT'S CONDITION RELATED TO:

a. EMPLOYMENT? (Current or Previous) YES [ ] NO [X]

b. AUTO ACCIDENT? YES [ ] NO [X] PLACE (State)

c. OTHER ACCIDENT? YES [ ] NO [X]

(Designated by NUCC)

11. INSURED'S POLICY GROUP OR FECA NUMBER: 11111

a. INSURED'S DATE OF BIRTH MM DD YY: 06 01 1930 — SEX: M [ ] F [X]

b. OTHER CLAIM ID (Designated by NUCC): ABC Employer

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES [ ] NO [X] *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM. or other information necessary y who accepts assignment

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

16. DATES PA... MM DD YY — FROM

18. HOSPIT... FROM

19. ADDITIONAL CLAIM INFORMATION (D... Prolia® (denosumab)

20. OUTSID... YE...

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

A. M81.0 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBM... CODE

23. PRIOR AU...

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		NPI	
2 01 23 14	01 23 14	11		96372			XXX XX	1		NPI	
										NPI	
										NPI	
										NPI	
										NPI	
										NPI	

SSN EIN [X]

TAL CHARGE: XXX XX — 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 part thereof.)

SIGNED — DATE: 08-22-17

32. SERVICE FACILITY LOCATION INFORMATION

a. XXXXXXXXX b.

33. BILLING PROVIDER INFO & PH # ( )

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 19. Additional Claim Information: Indicate Prolia® (denosumab) 60 mg

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 for use of a 60 mg prefilled syringe of Prolia®

Indicate 1 for the CPT code

Box 24A. Dates of Service: Medicaid and commercial payers may require NDC reporting for Prolia® submissions.

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® (denosumab) Coding Information

Additional Claim Information in Box 19: (Electronic Form: Loop 2300, or 2400, NTE, 02)[1]	• **Prolia®** (denosumab) 60 mg
Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)[1]	• **HCPCS code (J-code): J0897** (injection, denosumab 1 mg)[2] • **NDC number: 55513-0710-01**[3]
Number of Units in Box 24G: (Electronic Form: Loop 2400, SV1, 04[03 = UN])[1]	Use of a 60 mg prefilled syringe of Prolia® is reported as: • **60 units**

Diagnosis/Condition Coding Information*

ICD-10-CM Code in Box 21: (Electronic Form: Loop 2300, HI, 01-2)[1]	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. Sample factors appear below: **Cancer Diagnosis:** • **C61** (malignant neoplasm of prostate)[4] **Use of Androgen Deprivation or Aromatase Inhibitor Therapy:** • **Z79.818** (long-term [current] use of other agents affecting estrogen receptors and estrogen levels)[4,†] OR • **Z79.899** (other long-term [current] drug therapy)[4] **Other Risk Factors for Fracture:** • **M85.9** (disorder of bone density and structure, unspecified)[4,‡]

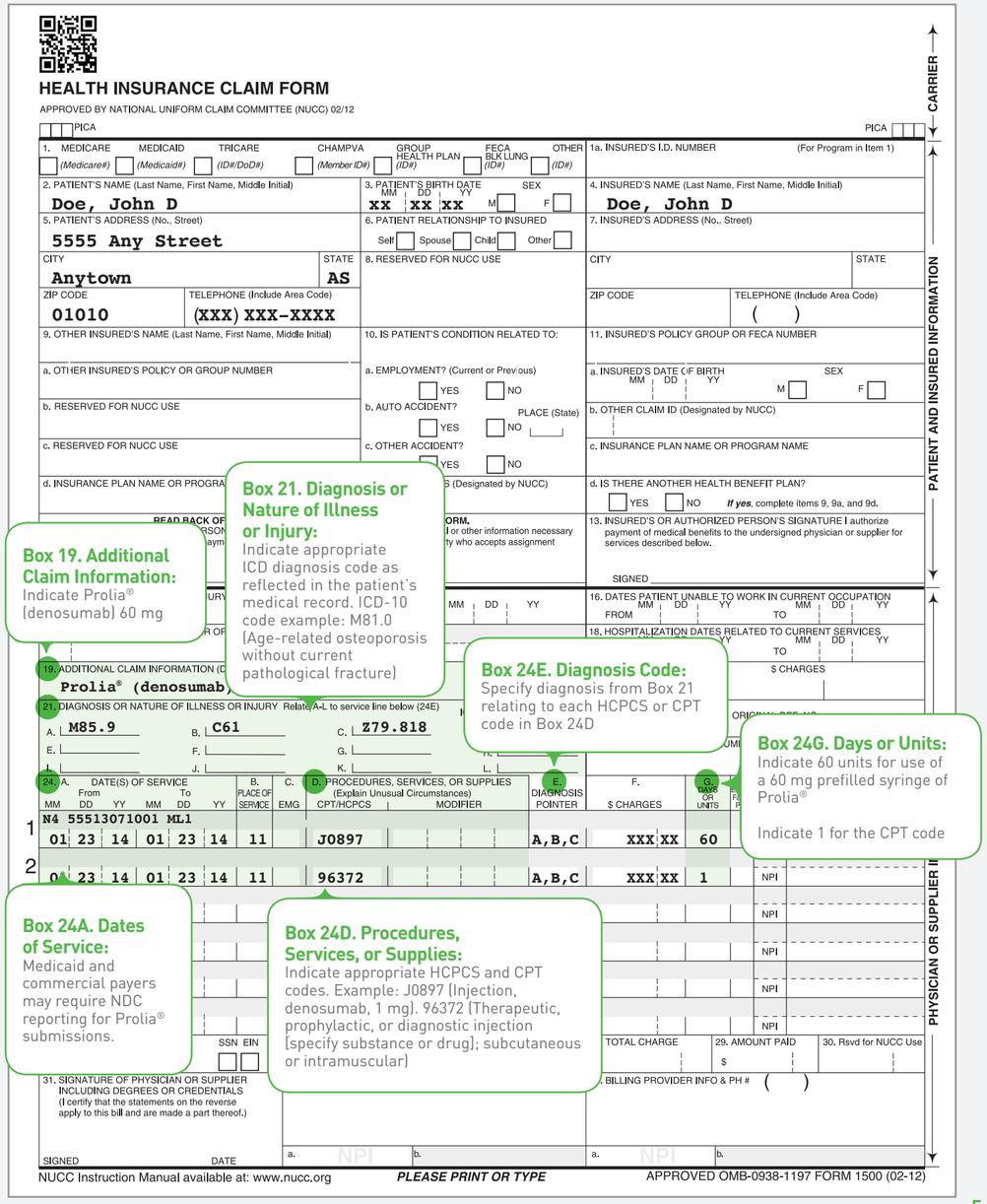
Administration and Professional Service Coding Information*

Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)[1]	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)[5] • **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). 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.
Considerations:	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®.

* 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.

† 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.



Box 19. Additional Claim Information: Indicate Prolia® (denosumab) 60 mg

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 24E. Diagnosis Code: Specify diagnosis from Box 21 relating to each HCPCS or CPT code in Box 24D

Box 24G. Days or Units: Indicate 60 units for use of a 60 mg prefilled syringe of Prolia®

Indicate 1 for the CPT code

Box 24A. Dates of Service: Medicaid and commercial payers may require NDC reporting for Prolia® submissions.

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)

Hospital/Institution Billing Information – Osteoporosis

Prolia® (denosumab) Coding Information

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)[7]	• **Medicare: 0636** (drugs requiring detailed coding)[8,9] • **Other Payers: 0250,** general pharmacy; OR **0636**, if required by a given payer[8]
Coding Information in Box 44: (Electronic Form: Loop 2400, SV202-2 [SV202-1 = HC/HP])[7]	• **HCPCS code (J-code): J0897** (subcutaneous injection, denosumab, 1 mg)[2] • **NDC number: 55513-0710-01**[3]
Service Units in Box 46: (Electronic Form: Loop 2400, SV205)[7]	• **60 units** (Prolia dose is 60 mg, per label)

Diagnosis/Condition Coding Information*

Revenue Code:	N/A
ICD-10-CM Code in Box 67: (Electronic Form: Loop 2300, HI01-2 [HI01-1 = BK])[7]	Document the appropriate ICD-10-CM code(s) for the patient's condition. Sequencing of codes may vary based on patient's condition and payer's policy. The following ICD-10-CM diagnosis code may be appropriate to describe patients *with* current osteoporotic fracture treated with Prolia®: • **M80.0** (Age-related osteoporosis with current pathological fracture)[4] Please see page 10 for additional examples of patients with current osteoporotic fracture. The following primary diagnosis codes may be appropriate for patients *without* current osteoporotic fracture treated with Prolia®: • **M81.0** (Age-related osteoporosis without current pathological fracture)[4,†] • **M81.8** (Other osteoporosis without current pathological fracture)[4,†] The following secondary diagnosis codes may be appropriate to describe patients for glucocorticoid-induced osteoporosis: • **T38.0X5** Adverse effect of glucocorticoids and synthetic analogues, sequela

Administration Coding Information*

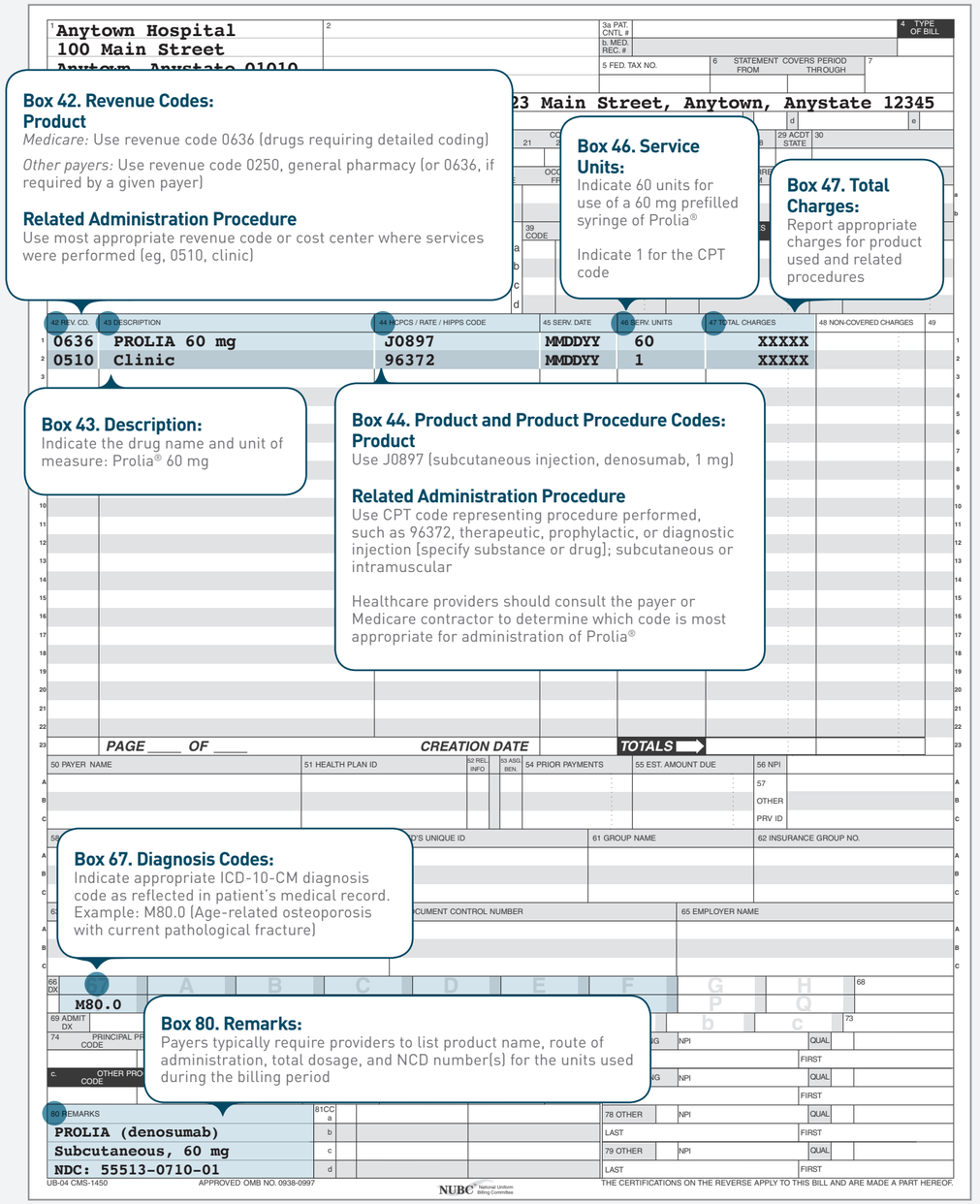
Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)[7]	Appropriate revenue code for the cost center in which the service is performed.
Coding Information in Box 43: (Electronic Form: Not required by Medicare)[7]	• **96372** (therapeutic, prophylactic or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)[5] • **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)

* 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.

† According to the ICD-10-CM Official Guidelines for Coding and Reporting, M81 code is for use with 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.[6]

Please see Important Safety Information on the back.

Completing the CMS 1450 for Hospital/Institutions – Osteoporosis



Hospital/Institution Billing Information – Cancer Treatment-induced Bone Loss (CTIBL)

Prolia® (denosumab) Coding Information

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)[7]	• **Medicare: 0636** (drugs requiring detailed coding)[8,9] • **Other Payers: 0250,** general pharmacy; OR **0636**, if required by a given payer[8]
Coding Information in Box 44: (Electronic Form: Loop 2400, SV202-2 [SV202-1 = HC/HP])[7]	• **HCPCS code (J-code): J0897** (subcutaneous injection, denosumab, 1 mg)[2] • **NDC number: 55513-0710-01**[3]
Service Units in Box 46: (Electronic Form: Loop 2400, SV205)[7]	• **60 units** (Prolia dose is 60 mg, per label) The NDC number covers both injections[3]

Diagnosis/Condition Coding Information*

Revenue Code:	N/A
ICD-10-CM Code in Box 67: (Electronic Form: Loop 2300, HI01-2 [HI01-1 = BK])[7]	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. Sample factors appear below: **Cancer Diagnosis:** • **C61** (malignant neoplasm of prostate)[4] **Use of Androgen Deprivation or Aromatase Inhibitor Therapy:** • **Z79.818** (long-term [current] use of other agents affecting estrogen receptors and estrogen levels)[4,†] OR • **Z79.899** (other long-term [current] drug therapy)[4] **Other Risk Factors for Fracture:** • **M85.9** (disorder of bone density and structure, unspecified)[4,‡]

Administration Coding Information*

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)[7]	Appropriate revenue code for the cost center in which the service is performed.
Coding Information in Box 44: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])[7]	The following codes 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)[5] • **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). 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.
Considerations:	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®.

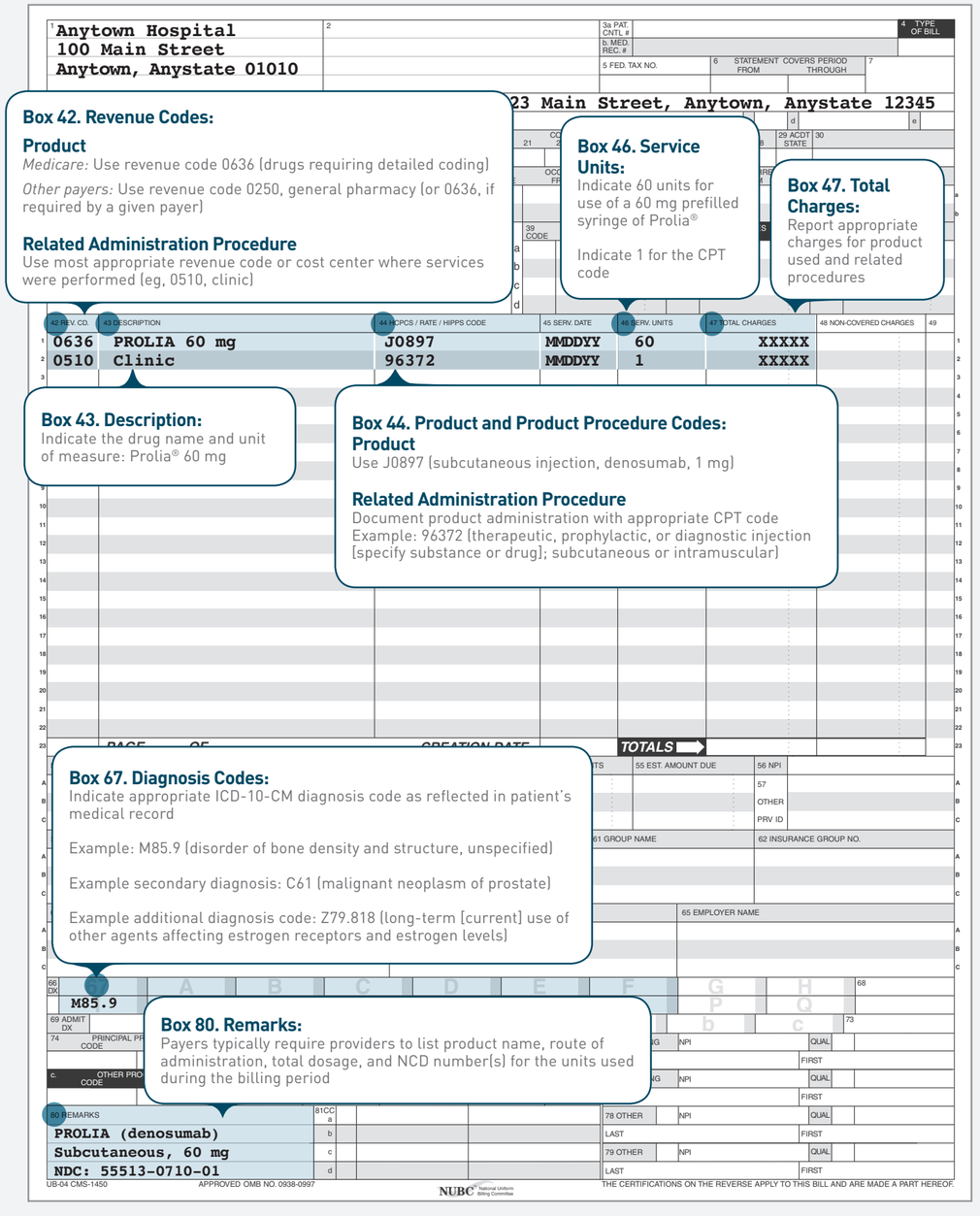
* The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for Prolia®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the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

† 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.

Please see Important Safety Information on the back.

Completing the CMS 1450 for Hospitals/Institutions – CTIBL



Box 42. Revenue Codes:

Product

Medicare: Use revenue code 0636 (drugs requiring detailed coding)

Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer)

Related Administration Procedure

Use most appropriate revenue code or cost center where services were performed (eg, 0510, clinic)

Box 46. Service Units:

Indicate 60 units for use of a 60 mg prefilled syringe of Prolia®

Indicate 1 for the CPT code

Box 47. Total Charges:

Report appropriate charges for product used and related procedures

Box 43. Description:

Indicate the drug name and unit of measure: Prolia® 60 mg

Box 44. Product and Product Procedure Codes:

Product

Use J0897 (subcutaneous injection, denosumab, 1 mg)

Related Administration Procedure

Document product administration with appropriate CPT code

Example: 96372 (therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)

Box 67. Diagnosis Codes:

Indicate appropriate ICD-10-CM diagnosis code as reflected in patient's medical record

Example: M85.9 (disorder of bone density and structure, unspecified)

Example secondary diagnosis: C61 (malignant neoplasm of prostate)

Example additional diagnosis code: Z79.818 (long-term [current] use of other agents affecting estrogen receptors and estrogen levels)

Box 80. Remarks:

Payers typically require providers to list product name, route of administration, total dosage, and NCD number(s) for the units used during the billing period

Examples of ICD-10-CM Codes Relevant for Patients With Current Osteoporotic Fracture Treated With Prolia®[4]

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 next page 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.[6]

† 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.[6]

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

Clinical Diagnosis Details	Potential ICD-10-CM Code[4]
Postmenopausal osteoporosis Vertebral fractures Encounter for evaluating and continuing treatment for the fractures	Age-related osteoporosis with current pathological fracture: **M80.08XA** — Initial encounter for fracture; Fracture of vertebrae

Clinical Diagnosis Details	Potential ICD-10-CM Code[4]
Postmenopausal osteoporosis Fracture of left wrist Follow-up encounter for routine fracture management (after active treatment has been completed)	Age-related osteoporosis with current pathological fracture: **M80.032D** — Left; Subsequent encounter for fracture with routine healing; Fracture of forearm

References:

1. Palmetto GBA. ASC 837 v5010 to CMS-1500 Crosswalk. http://www.palmettogba.com/Palmetto/Providers.Nsf/files/CMS1500_ 837v5010_Crosswalk.pdf/$File/CMS1500_837v5010_Crosswalk.pdf. Accessed October 30, 2019. **2.** HCPCS.codes. HCPCS J-codes. http://hcpcs.codes/j-codes/J0897/. Accessed October 30, 2019. **3.** Prolia® (denosumab) prescribing information, Amgen. **4.** Centers for Disease Control and Prevention. 2019 ICD-10-CM tabular list of diseases and injuries. In: International Classification of Disease, 10th Revision, Clinical Modification (ICD-10-CM). FY 2019. Full PDF. **5.** American Medical Association. 2017 Professional Edition, Current Procedural Terminology (CPT) copyright 2016 American Medical Association. All rights reserved. **6.** Centers for Medicare and Medicaid Services. ICD-10-CM official guidelines for coding and reporting, FY 2017. http://www. cdc.gov/nchs/data/icd/10cmguidelines_2017_final.pdf. Accessed October 30, 2019. **7.** Palmetto GBA. ASC 837I version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form crosswalk. http://www.palmettogba.com/Palmetto/Providers.Nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf. Accessed October 30, 2019. **8.** Value Healthcare Services. Understanding hospital revenue codes. http://valuehealthcareservices.com/education/understanding-hospital-revenue-codes/. Accessed October 30, 2019. **9.** Centers for Medicare & Medicaid Services. Publication 100-04: Medicare Claims Processing Manual. Chapter 17: drugs and biologicals. Section 80.9: required modifiers for ESAs administered to non-ESRD patients. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf. Accessed October 30, 2019.

Considerations for Complete Claim Submission

CORRECT AND COMPLETE PATIENT INFORMATION:

- ☐ Patient name
  - – ID number
  - – Health insurer name and/or group number
- ☐ Provider name
  - – National provider ID number
  - – Contact information

COLLECT PRODUCT AND BILLING INFORMATION:

- ☐ Correct HCPCS code and units
- ☐ Diagnosis code to the highest level of specificity
  - – Primary diagnosis code
- ☐ Identify appropriate administration code
- ☐ Determine prior authorization criteria (if required)
- ☐ Medicaid and commercial payers may require NDC reporting

SUPPLEMENTAL DOCUMENTATION CONSIDERATIONS (INCLUDING TEST RESULTS AND DATE AS APPROPRIATE):

- ☐ Original diagnostic T-score and/or FRAX predicted fracture risk
- ☐ Previous therapies
  - – Reason for discontinuations
- ☐ Calcium levels
- ☐ Prior osteoporosis-related fracture history
  - – Location of fracture (please provide ICD-10 number[s])
- ☐ Referring physician orders
- ☐ Risk factors for fracture

CONFIRM BILLING AND PAYER REQUIREMENTS:

- ☐ Omit or include punctuation as required in submitted claims
- ☐ Follow required time frame for submission after rendering service

ICD-10-CM CODE EXAMPLES

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. 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, including treatment with other calcium-lowering drugs, clinical monitoring of calcium and mineral levels is highly recommended within 14 days of Prolia® injection. Concomitant use of calcimimetic drugs may worsen hypocalcemia risk and serum calcium should be closely monitored. 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 antiresorptive 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 these 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.

  The most common adverse reactions (> 3% and more common than active-control group) in patients with glucocorticoid-induced osteoporosis are back pain, hypertension, bronchitis, and headache.

  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.

  Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

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

AMGEN®

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prolia® (denosumab) injection