PROLIA®
CODING AND BILLING INFORMATION GUIDE

For physician offices using the CMS 1500

For hospitals/institutions using the CMS 1450

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.

For 340B Entities: Beginning January 1, 2023, Medicare requires that all claims submitted by 340B covered entities on OPPS claims (bill type 13X) for separately payable Part B drugs and biologicals must include modifiers "JG" (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) or "TB" (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) on claim lines for drugs acquired through the 340B Drug Discount Program. Additional provider types will be required to use these modifiers in 2024.

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.

SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE:

Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following Prolia administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiating Prolia in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with Prolia in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Please see additional Important Safety Information on the back cover.

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)	• **Prolia®** (denosumab) 60 mg
Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)	• **HCPCS code (J-code): J0897** (injection, denosumab 1 mg) • **Select the appropriate NDC from the following as seen on the product carton:** **NDC number: 55513-710-01** **NDC number: 55513-710-21**
JW /JZ Modifier in Box 24D	Medicare Part B claims require the use of a JW or JZ modifier for single-dose containers to report discarded or no discarded drug amounts. **JW Modifier** -Drug amount discarded/not administered to any patient OR **JZ Modifier** -No discarded amounts Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.*
Number of Units in Box 24G: (Electronic Form: Loop 2400, SV1, 04 [03 = UN])	Use of a 60 mg prefilled syringe of Prolia® is reported as: • **60 units**

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

Diagnosis Coding Information*

ICD-10-CM Code in Box 21: (Electronic Form: Loop 2300, HI, 01-2)	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) – To ensure specificity, 3 additional characters should follow M80.0 to describe laterality, anatomic site, and encounter type See page 10 for coding details for 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) • **M81.8** (Other osteoporosis without current pathological fracture)
	The following secondary diagnosis code may be appropriate to describe patients with a personal history of healed osteoporosis fracture: • **Z87.310** Personal history of healed osteoporosis fracture
	The following secondary diagnosis code may be appropriate to describe patients for glucocorticoid-induced osteoporosis: • **Z79.52** (Long-term [current] use of systemic steroids)

Administration and Professional Service Coding Information*

Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)	Healthcare providers should consult the payer or Medicare contractor to determine the code most appropriate for administration. It is the provider's responsibility to ensure that codes used are consistent with payer policy and reflect the service performed. • Determine appropriate product administration CPT code • **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)

• For postmenopausal women and men with osteoporosis who are diagnosed as intolerant to other available osteoporosis therapies, consult the ICD-10-CM codes.

*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.

Please see Important Safety Information on the back cover.

Completing the CMS 1500 for Physician Offices – Osteoporosis

prolia® (denosumab) Injection

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 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):

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 MM DD YY: 06 01 1930 | SEX M [ ] F [X]

b. RESERVED FOR NUCC USE

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

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

c. RESERVED FOR NUCC USE

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

READ BACK OF FORM BEFORE COMPL... complete items 9, 9a, and 9d.

...RSON'S SIGNATURE I authorize ...undersigned physician or supplier for

16. D... FROM

18. H... SPIT... FROM

20. OUTSID... YE...

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): Prolia® (denosumab) 60 mg ML1

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. RESUBMISSION CODE | ORIGINAL REF. NO.

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 ML1 01 23 21	01 23 21	11		J0897	XX		XXX XX	60		NPI	
2 01 23 21	01 23 21	11		96XXX			XXX XX	1		NPI	
										NPI	
										NPI	
										NPI	
										NPI	

SSN EIN [ ] [X]

...R SUPPLIER ...EDENTIALS ...e reverse ...part thereof.)

...-01-23 DATE

...available at: w...

28. TOTAL CHARGE $ XXX XX | 29. AMOUNT PAID $ | 30. Rsvd for NUCC Use

33. BILLING PROVIDER INFO & PH # ( )
John Smith MD
2 Doctors Blvd
Hometown, MA 01234

a. XXXXXXXXX | b.

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. If required by the payer, enter additional information such as the NDC.

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

Box 23. Prior Authorization number (if applicable)

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:
If NDC reporting is required (i.e., for Medicaid and some commercial payers), enter NDC for Prolia® in shaded portion of Item 24A above the date of service. Check with the payer to determine the proper format for NDC reporting

Box 24D. Product and Procedure Codes: Product (CPT/HCPCS)
Use J0897 (subcutaneous injection, denosumab, 1 mg)

JW/JZ Discard Modifier
JW (discarded units) or JZ (no discarded units) modifier required in the Modifier box for Medicare Part B claims for drugs in single-use containers (i.e., JZ)

Related Administration Procedure
Determine appropriate product administration CPT code

Physician Office Billing Information – Cancer Treatment-Induced Bone Loss (CTIBL)

Prolia® (denosumab) Coding Information

Additional Claim Information in Box 19: (Electronic Form: Loop 2300, or 2400, NTE, 02)	• **Prolia®** (denosumab) 60 mg
Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)	• **HCPCS code (J-code): J0897** (injection, denosumab 1 mg) • **Select the appropriate NDC from the following as seen on the product carton:** **NDC number: 55513-710-01** **NDC number: 55513-710-21**
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Number of Units in Box 24G: (Electronic Form: Loop 2400, SV1, 04[03 = UN])	Use of a 60 mg prefilled syringe of Prolia® is reported as: • **60 units**

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

Diagnosis/Condition Coding Information*

ICD-10-CM Code in Box 21: (Electronic Form: Loop 2300, HI, 01-2)	Payer coding requirements for men receiving androgen deprivation therapy for nonmetastatic prostate cancer or women receiving adjuvant aromatase inhibitor therapy for breast cancer will vary, including the order the codes must be reported. Sample codes are suggested below: Codes for Prolia® use to prevent bone loss associated with treatment for prostate or breast cancer. **Codes for Cancer Diagnosis:** • **C61** (Malignant neoplasm of prostate) Or • Provider to determine appropriate site and laterality for breast cancer diagnosis ICD-10 code **Use of Androgen Deprivation Therapy:** • **Z79.818** (Long-term [current] use or other agents affecting estrogen receptors and estrogen levels]† **Use of Aromatase Inhibitor Therapy:** • **Z79.811** (Long-term [current] use of aromatase inhibitors) **Bone codes that may be used (Consult individual payer requirements):** • **M85.9** (Disorder of bone density and structure, unspecified]‡ • **M81.0** (Age-related osteoporosis without current pathologic fracture) • **M81.8** (Other osteoporosis without pathologic fracture) • **M80.0_ _ _** (Age-related osteoporosis with current pathologic fracture) • **M80.8_ _ _** (Other osteoporosis with current pathological fracture)

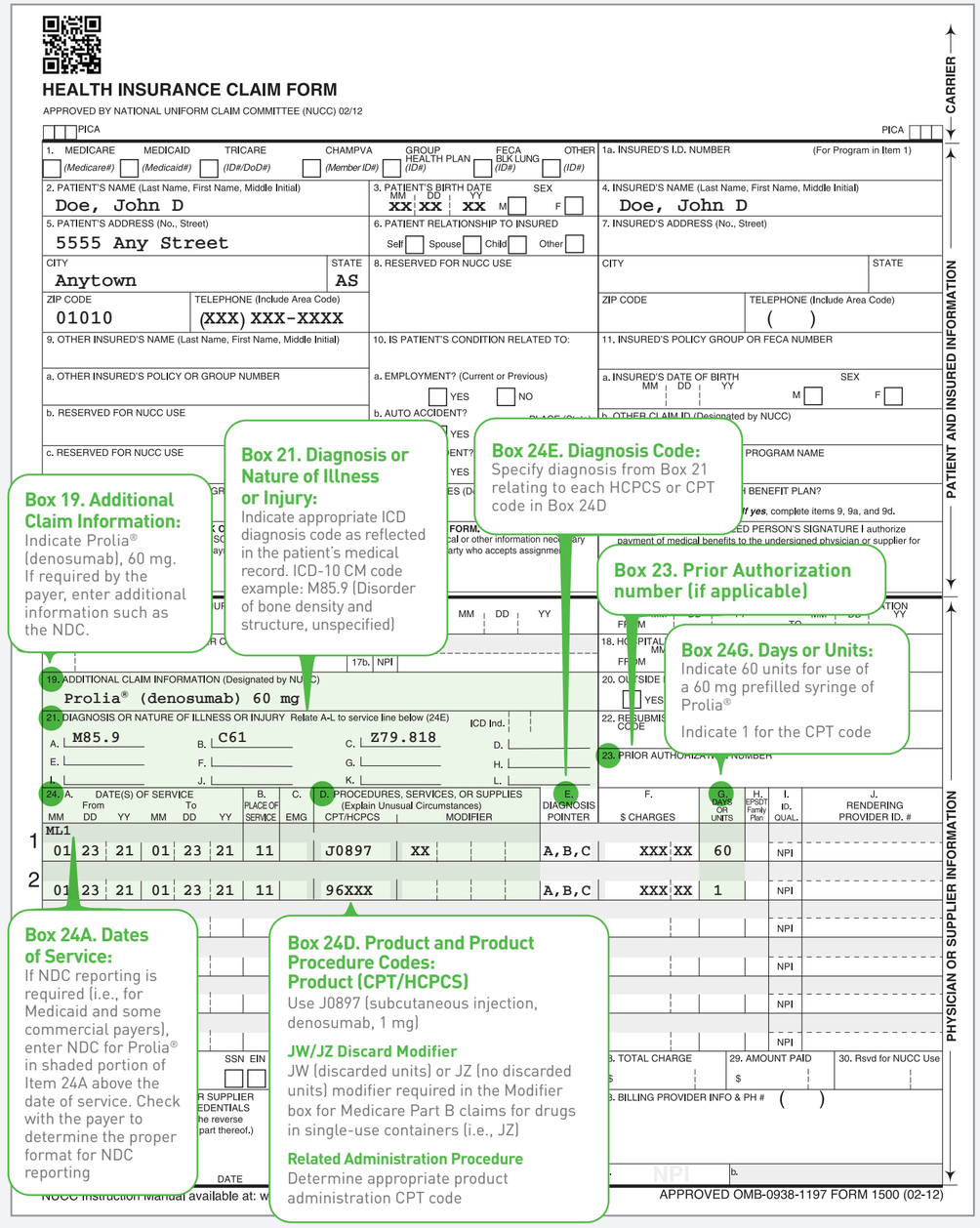
Administration and Professional Service Coding Information*

Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)	Healthcare providers should consult the payer or Medicare contractor to determine the code most appropriate for administration. It is the provider's responsibility to ensure that codes used are consistent with payer policy and reflect the service performed. • Determine appropriate product administration CPT code • **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.

*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 cover.

Completing the CMS 1500 for Physician Offices – CTIBL



Box 19. Additional Claim Information:
Indicate Prolia® (denosumab), 60 mg. If required by the payer, enter additional information such as the NDC.

Box 21. Diagnosis or Nature of Illness or Injury:
Indicate appropriate ICD diagnosis code as reflected in the patient's medical record. ICD-10 CM code example: M85.9 (Disorder of bone density and structure, unspecified)

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

Box 23. Prior Authorization number (if applicable)

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:
If NDC reporting is required (i.e., for Medicaid and some commercial payers), enter NDC for Prolia® in shaded portion of Item 24A above the date of service. Check with the payer to determine the proper format for NDC reporting

Box 24D. Product and Product Procedure Codes: Product (CPT/HCPCS)
Use J0897 (subcutaneous injection, denosumab, 1 mg)

JW/JZ Discard Modifier
JW (discarded units) or JZ (no discarded units) modifier required in the Modifier box for Medicare Part B claims for drugs in single-use containers (i.e., JZ)

Related Administration Procedure
Determine appropriate product administration CPT code

Hospital/Institution Billing Information – Osteoporosis

Prolia® (denosumab) Coding Information

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)	• **Medicare: 0636** (drugs requiring detailed coding) • **Other Payers: 0250,** general pharmacy; OR **0636**, if required by a given payer
Coding Information in Box 44: (Electronic Form: Loop 2400, SV202-2 [SV202-1 = HC/HP])	• **HCPCS code (J-code): J0897** (subcutaneous injection, denosumab, 1 mg) • **Select the appropriate NDC from the following as seen on the product carton:** **NDC number: 55513-710-01** **NDC number: 55513-710-21**
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Service Units in Box 46: (Electronic Form: Loop 2400, SV205)	• **60 units** (Prolia® dose is 60 mg, per label)

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

Diagnosis/Condition Coding Information*

Revenue Code:	N/A
ICD-10-CM Code in Box 67: (Electronic Form: Loop 2300, HI01-2 [HI01-1 = BK])	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) – To ensure specificity, 3 additional characters should follow M80.0 to describe laterality, anatomic site, and encounter type Refer to page 10 for coding details for 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) • **M81.8** (Other osteoporosis without current pathological fracture) The following secondary diagnosis code may follow the M81 category to describe patients with a personal history of healed osteoporosis fracture: • **Z87.310** Personal history of healed osteoporosis fracture The following secondary diagnosis codes may be appropriate to describe patients for glucocorticoid-induced osteoporosis: • **Z79.52** (Long-term [current] use of systemic steroids)

Administration Coding Information*

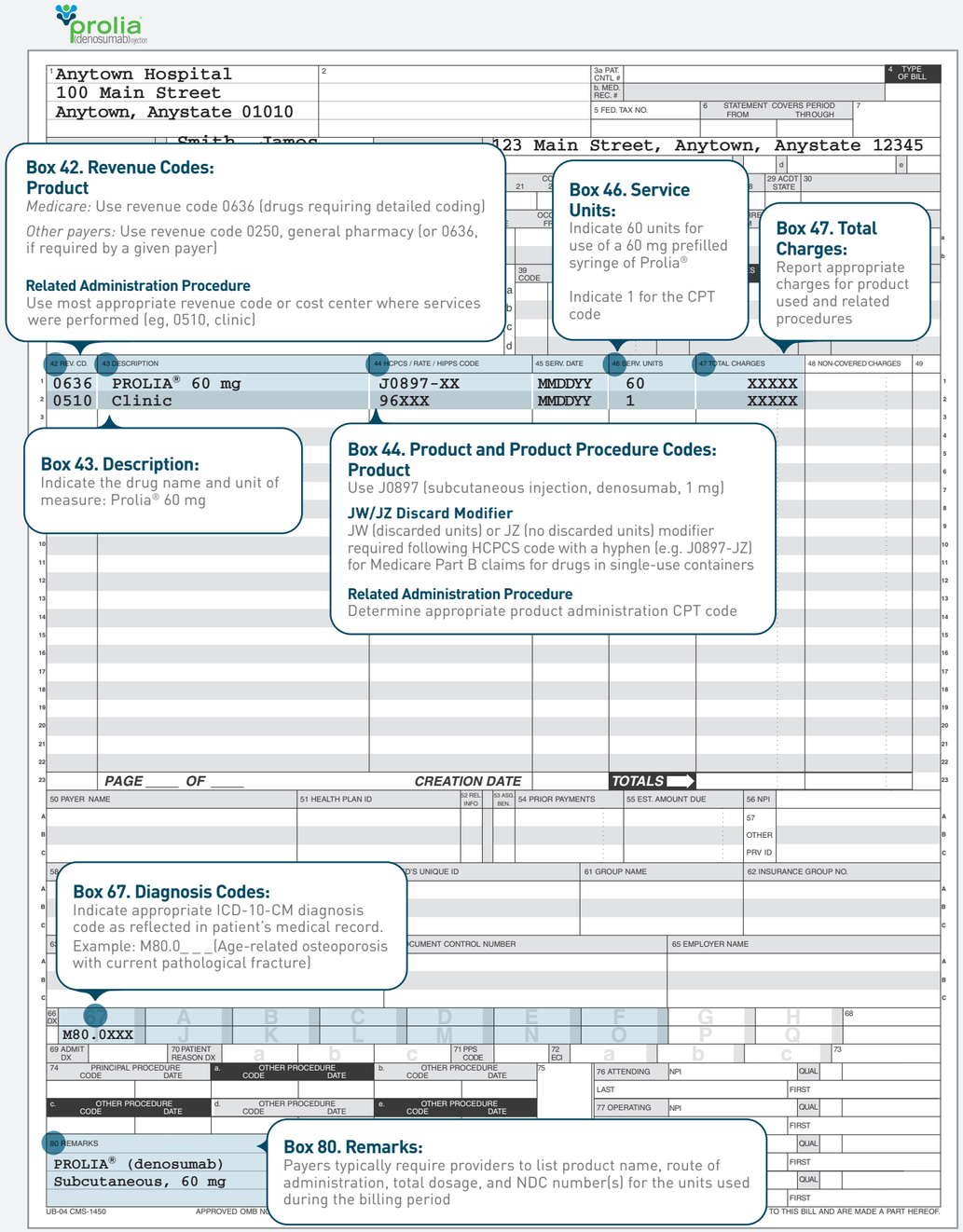
Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)	Appropriate revenue code for the cost center in which the service is performed.
Coding Information in Box 43: (Electronic Form: Not required by Medicare)	Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of Prolia® • Determine appropriate product administration CPT code • **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)

• For postmenopausal women and men with osteoporosis who are diagnosed as intolerant to other available osteoporosis therapies, consult the ICD-10-CM codes.

*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.

Please see Important Safety Information on the back cover.

Completing the CMS 1450 for Hospital/Institutions – Osteoporosis



Prolia® (denosumab) Coding Information

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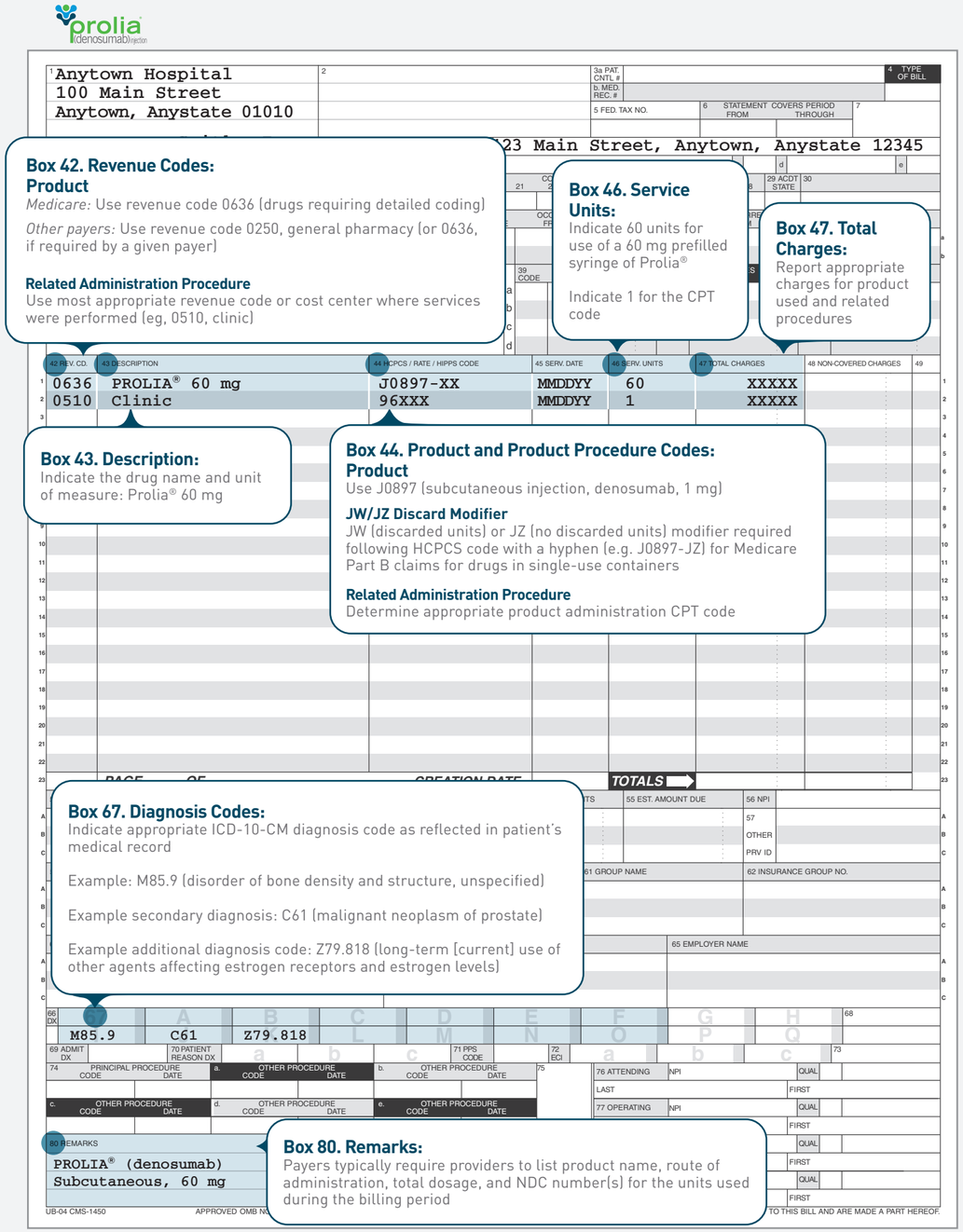


Examples of ICD-10-CM Codes Relevant for Patients With Current Osteoporotic Fracture Treated With Prolia® (denosumab)

Age-related osteoporosis with current pathological fracture

M80.0_ _ _ [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
PELVIS						
Right	M80.0B1A	M80.0B1D	M80.0B1G	M90.0B1K	M80.0B1P	M80.0B1S
Left	M80.0B2A	M80.0B2D	M80.0B2G	M80.0B2K	M80.0B2P	M80.0B2S
Unspecified	M80.0B9A	M80.0B9D	M80.0B9G	M80.0B9K	M80.0B9P	M80.0B9S
VERTEBRA(E)	M80.08XA	M80.08XD	M80.08XG	M80.08XK	M80.08XP	M80.08XS
OTHER SITE	M80.0AXA	M80.0AXD	M80.0AXG	M80.0AXK	M80.0AXP	M80.0AXS

For other osteoporosis with or without current Pathological fracture refer to ICD-10 reference.

*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.

†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.

‡Osteoporotic fracture of femur is the approximate synonym of osteoporotic fracture of the hip.

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

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

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

*The diagnosis code examples and the hypothetical scenarios above 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.

prolia® (denosumab) injection

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:

- ☐ CPT/HCPCS code (J-Code) and units
- ☐ Determine appropriate JW or JZ modifier
- ☐ 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 and Vitamin D
- ☐ Prior osteoporosis-related fracture history
  - Location of fracture (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

- **SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE:**

  Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following Prolia administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiating Prolia in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with Prolia in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.
- **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.
- **Severe Hypocalcemia and Mineral Metabolism Changes:** Prolia can cause severe hypocalcemia and fatal cases have been reported. Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia. Adequately supplement all patients with calcium and vitamin D.

  In patients without advanced chronic kidney disease who are predisposed to hypocalcemia and disturbances of mineral metabolism (e.g. treatment with other calcium-lowering drugs), assess serum calcium and mineral levels (phosphorus and magnesium) 10 to 14 days after Prolia injection.
- **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®.
- **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, patients should be transitioned to an alternative antiresorptive therapy.
- **Serious Infections:** In a clinical trial (N=7808), 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:** 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:** 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.

  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 scan the QR code or visit www.prolia.com/PI for Prolia® full Prescribing Information, including Boxed Warning and Medication Guide.

AMGEN®

Amgen
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
www.amgen.com

prolia® (denosumab) injection

PROLIA®
CODING AND BILLING INFORMATION GUIDE

For physician offices using the CMS 1500

For hospitals/institutions using the CMS 1450

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.

For 340B Entities: Beginning January 1, 2023, Medicare requires that all claims submitted by 340B covered entities on OPPS claims (bill type 13X) for separately payable Part B drugs and biologicals must include modifiers "JG" (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) or "TB" (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) on claim lines for drugs acquired through the 340B Drug Discount Program. Additional provider types will be required to use these modifiers in 2024.

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.

SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE:

Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following Prolia administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiating Prolia in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with Prolia in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Please see Important Safety Information on page 12.

prolia® (denosumab) injection

Prolia® (denosumab) Coding Information

Additional Claim Information in Box 19: (Electronic Form: Loop 2300, or 2400, NTE, 02)	• **Prolia®** (denosumab) 60 mg
Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)	• **HCPCS code (J-code): J0897** (injection, denosumab 1 mg) • **Select the appropriate NDC from the following as seen on the product carton:** **NDC number: 55513-710-01** **NDC number: 55513-710-21**
JW /JZ Modifier in Box 24D	Medicare Part B claims require the use of a JW or JZ modifier for single-dose containers to report discarded or no discarded drug amounts. **JW Modifier** -Drug amount discarded/not administered to any patient OR **JZ Modifier** -No discarded amounts Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.*
Number of Units in Box 24G: (Electronic Form: Loop 2400, SV1, 04 [03 = UN])	Use of a 60 mg prefilled syringe of Prolia® is reported as: • **60 units**

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

Diagnosis Coding Information*

ICD-10-CM Code in Box 21: (Electronic Form: Loop 2300, HI, 01-2)	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) – To ensure specificity, 3 additional characters should follow M80.0 to describe laterality, anatomic site, and encounter type See page 10 for coding details for 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) • **M81.8** (Other osteoporosis without current pathological fracture)
	The following secondary diagnosis code may be appropriate to describe patients with a personal history of healed osteoporosis fracture: • **Z87.310** Personal history of healed osteoporosis fracture
	The following secondary diagnosis code may be appropriate to describe patients for glucocorticoid-induced osteoporosis: • **Z79.52** (Long-term [current] use of systemic steroids)

Administration and Professional Service Coding Information*

Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)	Healthcare providers should consult the payer or Medicare contractor to determine the code most appropriate for administration. It is the provider's responsibility to ensure that codes used are consistent with payer policy and reflect the service performed. • Determine appropriate product administration CPT code • **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)

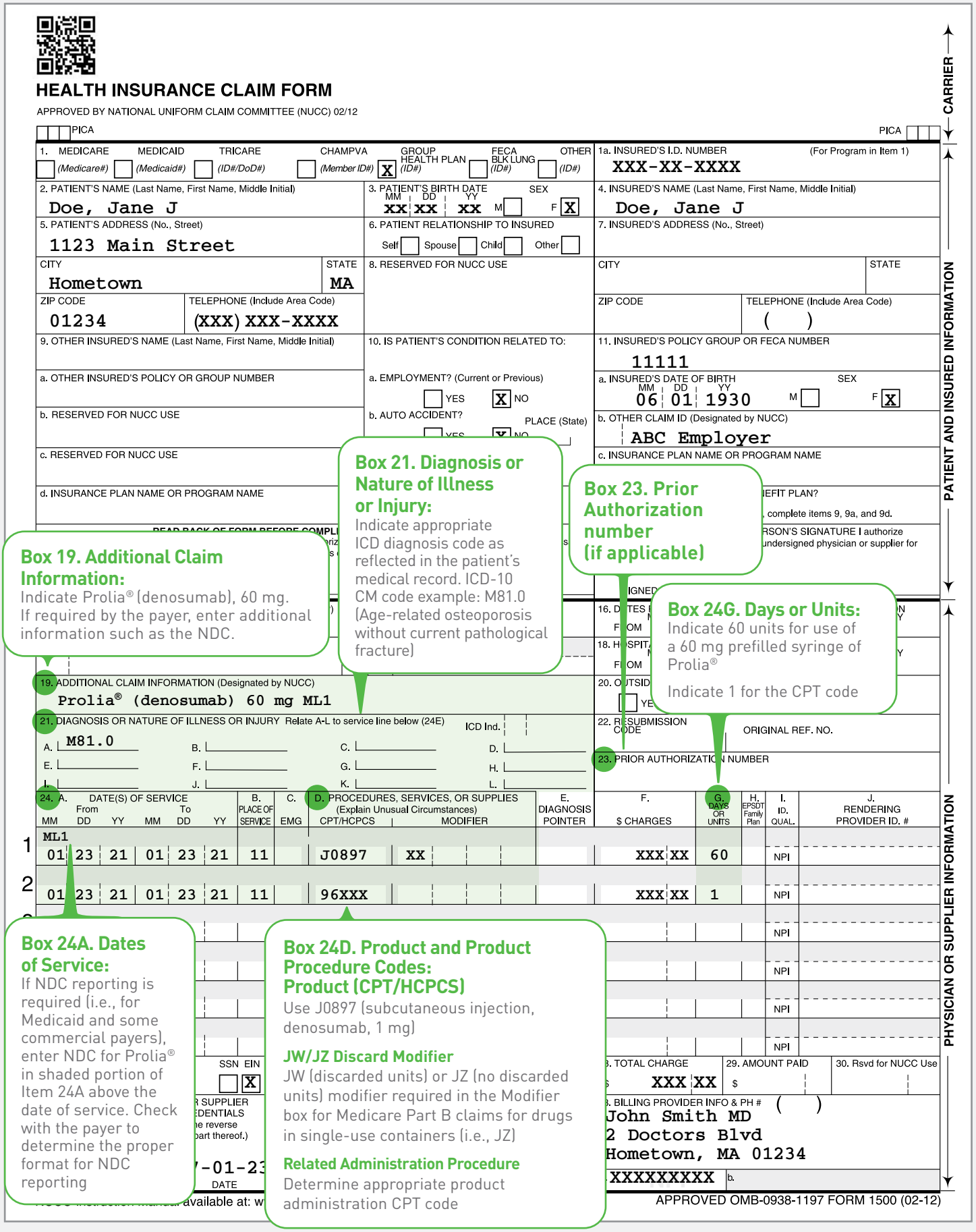
• For postmenopausal women and men with osteoporosis who are diagnosed as intolerant to other available osteoporosis therapies, consult the ICD-10-CM codes.

*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.

Please see Important Safety Information on page 12.

Completing the CMS 1500 for Physician Offices – Osteoporosis

prolia® (denosumab) injection



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):

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 MM DD YY: 06 01 1930 SEX M [ ] F [X]

b. RESERVED FOR NUCC USE

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

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

c. RESERVED FOR NUCC USE

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

...EFIT PLAN? ..., complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPL... ...RSON'S SIGNATURE I authorize ...undersigned physician or supplier for

...IGNED

16. DATES ... FROM ... N Y

18. HOSPIT... FROM ... Y

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): Prolia® (denosumab) 60 mg ML1

20. OUTSID... YES [ ]

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. RESUBMISSION CODE ORIGINAL REF. NO.

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 ML1 01	23	21	01	23	21	11		J0897	XX		XXX	XX	60		NPI
2 01	23	21	01	23	21	11		96XXX			XXX	XX	1		NPI
															NPI
															NPI
															NPI
															NPI

SSN EIN [X]

...R SUPPLIER ...EDENTIALS ...he reverse ...part thereof.)

...-01-23 DATE

...TOTAL CHARGE $ XXX XX | 29. AMOUNT PAID $ | 30. Rsvd for NUCC Use

...BILLING PROVIDER INFO & PH # ( )
John Smith MD
2 Doctors Blvd
Hometown, MA 01234

XXXXXXXXX b.

...available at: w...

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. If required by the payer, enter additional information such as the NDC.

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

Box 23. Prior Authorization number (if applicable)

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:
If NDC reporting is required (i.e., for Medicaid and some commercial payers), enter NDC for Prolia® in shaded portion of Item 24A above the date of service. Check with the payer to determine the proper format for NDC reporting

Box 24D. Product and Product Procedure Codes: Product (CPT/HCPCS)
Use J0897 (subcutaneous injection, denosumab, 1 mg)

JW/JZ Discard Modifier
JW (discarded units) or JZ (no discarded units) modifier required in the Modifier box for Medicare Part B claims for drugs in single-use containers (i.e., JZ)

Related Administration Procedure
Determine appropriate product administration CPT code

Prolia® (denosumab) Coding Information

Additional Claim Information in Box 19: (Electronic Form: Loop 2300, or 2400, NTE, 02)	• **Prolia®** (denosumab) 60 mg
Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)	• **HCPCS code (J-code): J0897** (injection, denosumab 1 mg) • **Select the appropriate NDC from the following as seen on the product carton:** **NDC number: 55513-710-01** **NDC number: 55513-710-21**
JW /JZ Modifier in Box 24D	Medicare Part B claims require the use of a JW or JZ modifier for single-dose containers to report discarded or no discarded drug amounts. **JW Modifier** -Drug amount discarded/not administered to any patient OR **JZ Modifier** -No discarded amounts Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.*
Number of Units in Box 24G: (Electronic Form: Loop 2400, SV1, 04[03 = UN])	Use of a 60 mg prefilled syringe of Prolia® is reported as: • **60 units**

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

Diagnosis/Condition Coding Information*

ICD-10-CM Code in Box 21: (Electronic Form: Loop 2300, HI, 01-2)	Payer coding requirements for men receiving androgen deprivation therapy for nonmetastatic prostate cancer or women receiving adjuvant aromatase inhibitor therapy for breast cancer will vary, including the order the codes must be reported. Sample codes are suggested below: Codes for Prolia® use to prevent bone loss associated with treatment for prostate or breast cancer. **Codes for Cancer Diagnosis:** • **C61** (Malignant neoplasm of prostate) Or • Provider to determine appropriate site and laterality for breast cancer diagnosis ICD-10 code **Use of Androgen Deprivation Therapy:** • **Z79.818** (Long-term [current] use or other agents affecting estrogen receptors and estrogen levels]† **Use of Aromatase Inhibitor Therapy:** • **Z79.811** (Long-term [current] use of aromatase inhibitors) **Bone codes that may be used (Consult individual payer requirements):** • **M85.9** (Disorder of bone density and structure, unspecified)‡ • **M81.0** (Age-related osteoporosis without current pathologic fracture) • **M81.8** (Other osteoporosis without pathologic fracture) • **M80.0_ _ _** (Age-related osteoporosis with current pathologic fracture) • **M80.8_ _ _** (Other osteoporosis with current pathological fracture)

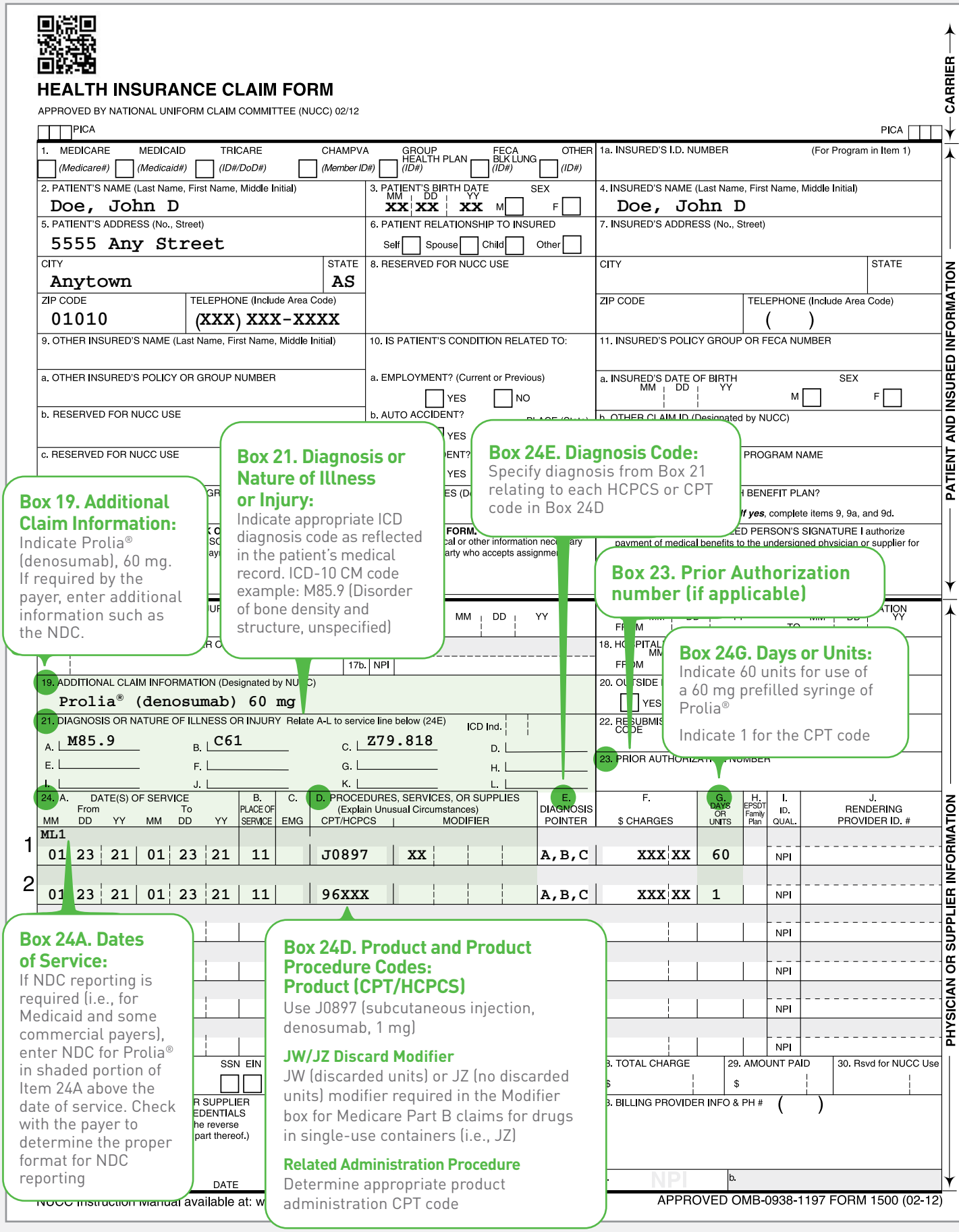
Administration and Professional Service Coding Information*

Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)	Healthcare providers should consult the payer or Medicare contractor to determine the code most appropriate for administration. It is the provider's responsibility to ensure that codes used are consistent with payer policy and reflect the service performed. • Determine appropriate product administration CPT code • **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.

*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 page 12.

prolia® (denosumab) injection



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

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

YES

PROGRAM NAME

BENEFIT PLAN?

If yes, complete items 9, 9a, and 9d.

ED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for

MM DD YY

17b. NPI

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
Prolia® (denosumab) 60 mg

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.

22. RESUBMIS CODE

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. #
ML1															
1 01	23	21	01	23	21	11		J0897	XX	A,B,C	XXX	XX 60		NPI	
2 01	23	21	01	23	21	11		96XXX		A,B,C	XXX	XX 1		NPI	
														NPI	
														NPI	
														NPI	
														NPI	
														NPI	

SSN EIN

26. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

R SUPPLIER EDENTIALS he reverse part thereof.)

33. BILLING PROVIDER INFO & PH # ( )

DATE

NPI b.

NUCC Instruction Manual available at: w

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. If required by the payer, enter additional information such as the NDC.

Box 21. Diagnosis or Nature of Illness or Injury:
Indicate appropriate ICD diagnosis code as reflected in the patient's medical record. ICD-10 CM code example: M85.9 (Disorder of bone density and structure, unspecified)

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

Box 23. Prior Authorization number (if applicable)

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:
If NDC reporting is required (i.e., for Medicaid and some commercial payers), enter NDC for Prolia® in shaded portion of Item 24A above the date of service. Check with the payer to determine the proper format for NDC reporting

Box 24D. Product and Product Procedure Codes: Product (CPT/HCPCS)
Use J0897 (subcutaneous injection, denosumab, 1 mg)

JW/JZ Discard Modifier
JW (discarded units) or JZ (no discarded units) modifier required in the Modifier box for Medicare Part B claims for drugs in single-use containers (i.e., JZ)

Related Administration Procedure
Determine appropriate product administration CPT code

Please see Important Safety Information on page 12.

Hospital/Institution Billing Information – Osteoporosis

Prolia® (denosumab) Coding Information

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)	• **Medicare: 0636** (drugs requiring detailed coding) • **Other Payers: 0250,** general pharmacy; OR **0636**, if required by a given payer
Coding Information in Box 44: (Electronic Form: Loop 2400, SV202-2 [SV202-1 = HC/HP])	• **HCPCS code (J-code): J0897** (subcutaneous injection, denosumab, 1 mg) • **Select the appropriate NDC from the following as seen on the product carton:** **NDC number: 55513-710-01** **NDC number: 55513-710-21**
JW /JZ Modifier in Box 24D	Medicare Part B claims require the use of a JW or JZ modifier for single-dose containers to report discarded or no discarded drug amounts. **JW Modifier** -Drug amount discarded/not administered to any patient OR **JZ Modifier** -No discarded amounts Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.*
Service Units in Box 46: (Electronic Form: Loop 2400, SV205)	• **60 units** (Prolia® dose is 60 mg, per label)

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

Diagnosis/Condition Coding Information*

Revenue Code:	N/A
ICD-10-CM Code in Box 67: (Electronic Form: Loop 2300, HI01-2 [HI01-1 = BK])	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) – To ensure specificity, 3 additional characters should follow M80.0 to describe laterality, anatomic site, and encounter type Refer to page 10 for coding details for 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) • **M81.8** (Other osteoporosis without current pathological fracture)
	The following secondary diagnosis code may follow the M81 category to describe patients with a personal history of healed osteoporosis fracture: • **Z87.310** Personal history of healed osteoporosis fracture
	The following secondary diagnosis codes may be appropriate to describe patients for glucocorticoid-induced osteoporosis: • **Z79.52** (Long-term [current] use of systemic steroids)

Administration Coding Information*

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)	Appropriate revenue code for the cost center in which the service is performed.
Coding Information in Box 43: (Electronic Form: Not required by Medicare)	Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of Prolia® • Determine appropriate product administration CPT code • **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)

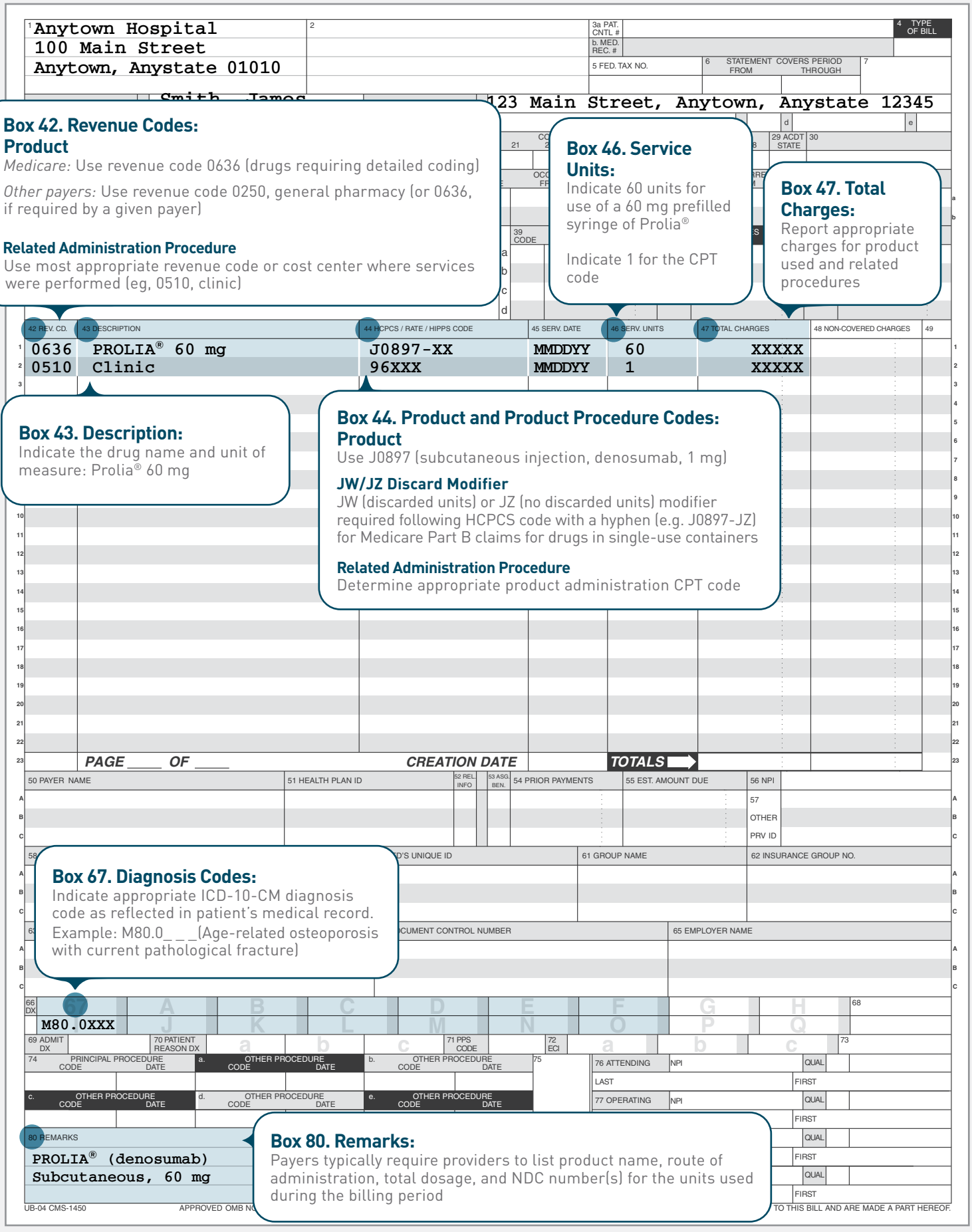
• For postmenopausal women and men with osteoporosis who are diagnosed as intolerant to other available osteoporosis therapies, consult the ICD-10-CM codes.

*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.

Please see Important Safety Information on page 12.

Completing the CMS 1450 for Hospital/Institutions – Osteoporosis

prolia® (denosumab) injection



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)

JW/JZ Discard Modifier

JW (discarded units) or JZ (no discarded units) modifier required following HCPCS code with a hyphen (e.g. J0897-JZ) for Medicare Part B claims for drugs in single-use containers

Related Administration Procedure

Determine appropriate product administration CPT code

Box 67. Diagnosis Codes:

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

Example: M80.0_ _ _(Age-related osteoporosis with current pathological fracture)

Box 80. Remarks:

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

Prolia® (denosumab) Coding Information

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)	• **Medicare: 0636** (drugs requiring detailed coding) • **Other Payers: 0250,** general pharmacy; OR **0636**, if required by a given payer
Coding Information in Box 44: (Electronic Form: Loop 2400, SV202-2 [SV202-1 = HC/HP])	• **HCPCS code (J-code): J0897** (subcutaneous injection, denosumab, 1 mg) • **Select the appropriate NDC from the following as seen on the product carton:** **NDC number: 55513-710-01** **NDC number: 55513-710-21**
JW /JZ Modifier in Box 24D	Medicare Part B claims require the use of a JW or JZ modifier for single-dose containers to report discarded or no discarded drug amounts. **JW Modifier** -Drug amount discarded/not administered to any patient OR **JZ Modifier** -No discarded amounts Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.*
Service Units in Box 46: (Electronic Form: Loop 2400, SV205)	• **60 units** (Prolia® dose is 60 mg, per label)

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

Diagnosis/Condition Coding Information*

Revenue Code:	N/A
ICD-10-CM Code in Box 67: (Electronic Form: Loop 2300, HI01-2 [HI01-1 = BK])	Payer coding requirements for men receiving androgen deprivation therapy for nonmetastatic prostate cancer or women receiving adjuvant aromatase inhibitor therapy for breast cancer will vary, including the order the codes must be reported. Sample codes are suggested below: Codes for Prolia® use to prevent bone loss associated with treatment for prostate or breast cancer. **Codes for Cancer Diagnosis:** • **C61** (Malignant neoplasm of prostate) Or • Provider to determine appropriate site and laterality for breast cancer diagnosis ICD-10 code **Use of Androgen Deprivation Therapy:** • **Z79.818** (Long-term [current] use or other agents affecting estrogen receptors and estrogen levels]† **Use of Aromatase Inhibitor Therapy:** • **Z79.811** (Long-term [current] use of aromatase inhibitors) **Bone codes that may be used (Consult individual payer requirements):** • **M85.9** (Disorder of bone density and structure, unspecified)‡ • **M81.0** (Age-related osteoporosis without current pathologic fracture) • **M81.8** (Other osteoporosis without pathologic fracture) • **M80.0_ _ _** (Age-related osteoporosis with current pathologic fracture) • **M80.8_ _ _** (Other osteoporosis with current pathological fracture)

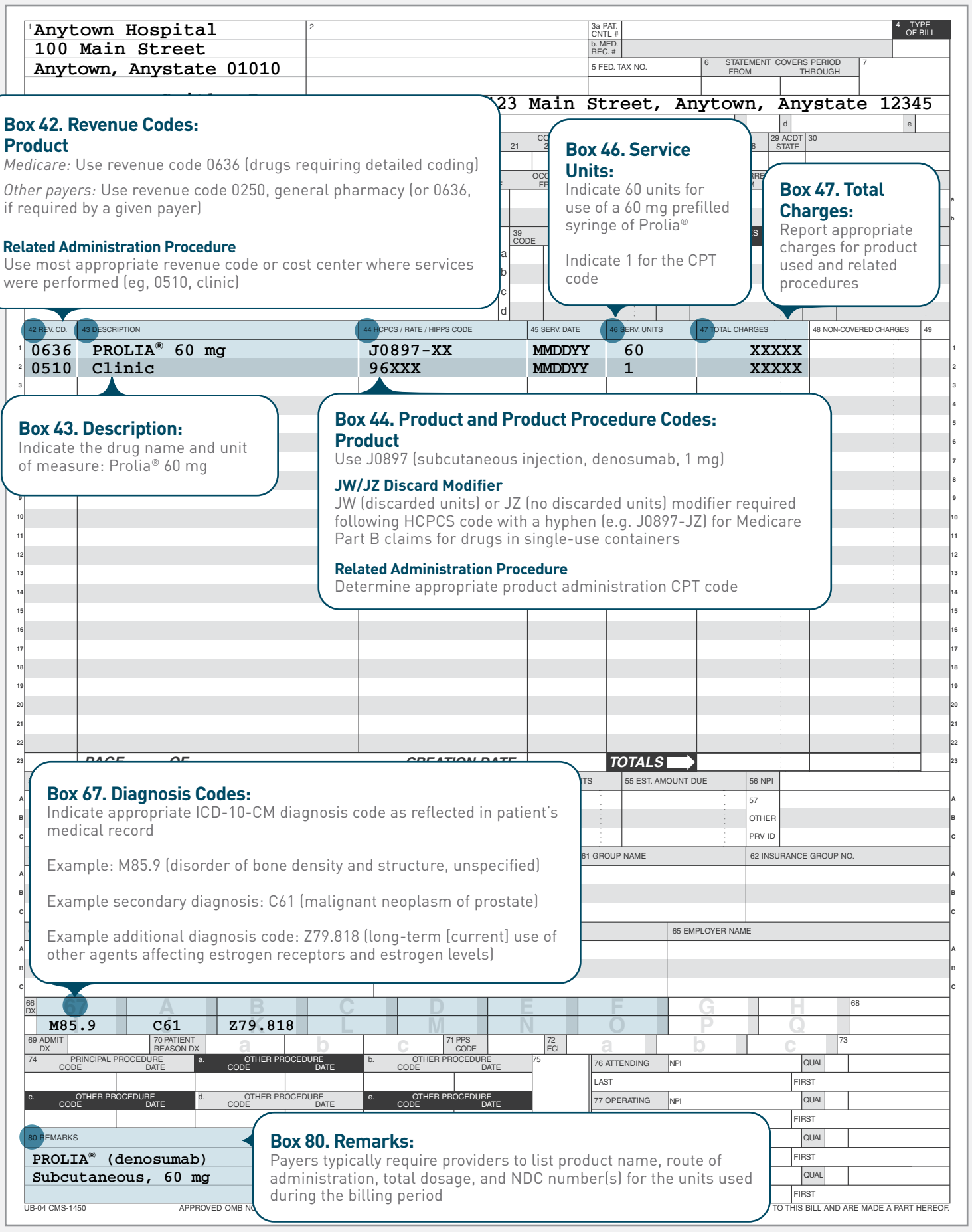
Administration Coding Information*

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)	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)	Healthcare providers should consult the payer or Medicare contractor to determine the code most appropriate for administration. It is the provider's responsibility to ensure that codes used are consistent with payer policy and reflect the service performed. • Determine appropriate product administration CPT code • **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.

*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 page 12.

prolia® (denosumab) injection



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)

JW/JZ Discard Modifier

JW (discarded units) or JZ (no discarded units) modifier required following HCPCS code with a hyphen (e.g. J0897-JZ) for Medicare Part B claims for drugs in single-use containers

Related Administration Procedure

Determine appropriate product administration CPT code

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 NDC number(s) for the units used during the billing period

Age-related osteoporosis with current pathological fracture

M80.0_ _ _ [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
PELVIS						
Right	M80.0B1A	M80.0B1D	M80.0B1G	M90.0B1K	M80.0B1P	M80.0B1S
Left	M80.0B2A	M80.0B2D	M80.0B2G	M80.0B2K	M80.0B2P	M80.0B2S
Unspecified	M80.0B9A	M80.0B9D	M80.0B9G	M80.0B9K	M80.0B9P	M80.0B9S
VERTEBRA[E]	M80.08XA	M80.08XD	M80.08XG	M80.08XK	M80.08XP	M80.08XS
OTHER SITE	M80.0AXA	M80.0AXD	M80.0AXG	M80.0AXK	M80.0AXP	M80.0AXS

For other osteoporosis with or without current Pathological fracture refer to ICD-10 reference.

*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.

†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.

‡Osteoporotic fracture of femur is the approximate synonym of osteoporotic fracture of the hip.

Please see Important Safety Information on page 12.

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

Clinical Diagnosis Details	Potential ICD-10-CM Code
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 Fracture of forearm Subsequent encounter for fracture with routine healing

*The diagnosis code examples and the hypothetical scenarios above 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.

Please see Important Safety Information on page 12.

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:

- ☐ CPT/HCPCS code (J-Code) and units
- ☐ Determine appropriate JW or JZ modifier
- ☐ 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 and Vitamin D
- ☐ Prior osteoporosis-related fracture history
  - – Location of fracture (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

- **SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE:**
  Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following Prolia administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiating Prolia in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with Prolia in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.
- **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.
- **Severe Hypocalcemia and Mineral Metabolism Changes:** Prolia can cause severe hypocalcemia and fatal cases have been reported. Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia. Adequately supplement all patients with calcium and vitamin D.
  In patients without advanced chronic kidney disease who are predisposed to hypocalcemia and disturbances of mineral metabolism (e.g. treatment with other calcium-lowering drugs), assess serum calcium and mineral levels (phosphorus and magnesium) 10 to 14 days after Prolia injection.
- **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®.
- **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, patients should be transitioned to an alternative antiresorptive therapy.
- **Serious Infections:** In a clinical trial (N=7808), 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:** 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:** 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.
  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 Prolia® full Prescribing Information, including Boxed Warning and Medication Guide.

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