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 solution provider types 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.

AMGEN[°]Support⁺

Call Amgen[®] SupportPlus at 1-866-264-2778 Monday - Friday, 9:00 am – 8:00 pm ET. Visit AmgenSupportPlus.com to learn how Amgen can help.

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.

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 |
| | 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 |
| JW /JZ Modifier in Box 24D | 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*

| | 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. |
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| ICD-10-CM Code in Box 21: (Electronic Form: Loop 2300, HI, 01-2) | The following primary diagnosis codes may be appropriate for patients <i>without</i> 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* |

| 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. |
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| 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) |
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• 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. 2

Completing the CMS 1500 for Physician Offices – Osteoporosis



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Related Administration Procedure

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APPROVED OMB-0938-1197 FORM 1500 (02-12)



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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 |
| 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*

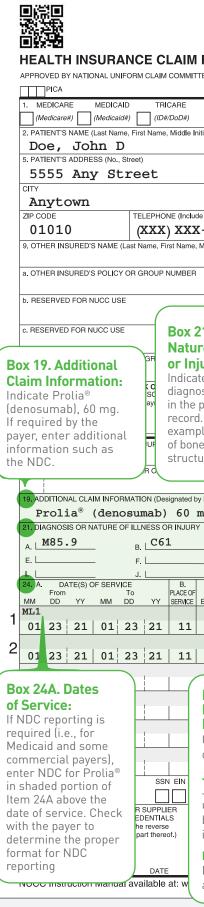
| ICD-10-CM Code in Box 21: (Electronic Form: Loop 2300, HI, 01-2) | Payer coding requirements for men receiving androgen deprivation therapy for nonmetastatic prostate cancer or women receiving adjuvant aromatase inhibitor therapy for breast cancer will vary, including the order the codes must be reported. 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) M80.0 (Age-related osteoporosis with current pathologic fracture) M80.8 (Other osteoporosis with current pathologic 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). 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 |

*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.

4 Please see Important Safety Information on the back cover.

Completing the CMS 1500 for Physician Offices – CTIBL





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| c. L | Z79.818 | L) ICD Ind. D. | i i | 22. RESUBMIS CODE | ndicate | 1 for the 0 | CPT code | |
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| | DURES, SERVIC | | ES E. DIAGNOSI POINTER | F. S \$ CHARGES | G. DAYS OR UNITS | H. I. EPSDT Family ID. Plan QUAL. | J. RENDERING PROVIDER ID. # | |
| J089 | | | A,B,C | | | NPI | | |
| 96xx | v | | A,B,C | xxx | 1 | NPI | | |
| JOAN | A | i i | A, B, C | | | | | |
| ox 24D | Product a | nd Prod | uct | | | NPI | | |
| rocedur | e Codes: | | | | | NPI | | |
| | CPT/HCP | | ion | | 1 | | | |
| enosumal | (subcutane o, 1 mg) | eous inject | 1011, | | | NPI | | |
| | ard Modifi | er | | | | NPI | | |
| W (discard nits) modi ox for Med | led units) c fier require dicare Part se containe | or JZ (no d ed in the N B claims | 1odifier for drugs | 3. TOTAL CHARGE | \$ | |) 30. Rsvd for NUCC | Use |
| i single-u: | | (I.E., J2 | -) | | | | | |

(YSICIAN OFFICE MS 1500) - CTIBL

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 |
| | 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 |
| JW /JZ Modifier in Box 24D | 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 |
|---|---|
| Revenue Code: ICD-10-CM Code in Box 67: [Electronic Form: Loop 2300, HI01-2 [HI01-1 = BK]] | N/A 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. 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. 6

Completing the CMS 1450 for Hospital/Institutions – Osteoporosis

'Anytown Hospital 100 Main Street Anytown, Anystate 01010

Box 42. Revenue Codes:

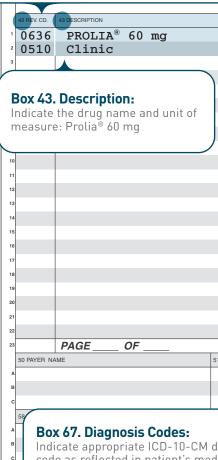
Product

Medicare: Use revenue code 0636 (drugs

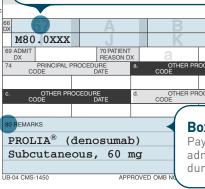
Other payers: Use revenue code 0250, gen if required by a given payer)

Related Administration Procedure

Use most appropriate revenue code or co were performed (eg, 0510, clinic)



code as reflected in patient's med Example: M80.0___(Age-related with current pathological fracture



| | - | | DAT | | 4 TVDE |
|---|--|---------------------------|-------------------------|------------------|---------------------------------------|
| spital | 2 | C | A PAT. NTL # MED. | | 4 TYPE OF BILL |
| reet | | R | EC. # | 6 STATEMEN | COVERS PERIOD 7 |
| ystate 01010 | | 5 | FED. TAX NO. | FROM | THROUGH |
| Smith Tamos | • • • | 122 Noin (| | | <u> </u> |
| | | 23 Main S | treet, A | nytown, | Anystate 12345 |
| odes: | | cq | | | d e |
| | | | 46. Service | 8 | 29 ACDT 30 STATE |
| e code 0636 (drugs r | equiring detailed coding) | | S: | | |
| enue code 0250 den | eral pharmacy (or 0636, | 000 | ate 60 units | for H | Box 47. Total |
| payer) | erat pharmacy (or 0000, | | of a 60 mg pr | | Charges: |
| payery | | svrin | ge of Prolia® | | Report appropriate |
| n Procedure | | 39 CODE | 5 | :5 | charges for product |
| | st center where services | a Indic | ate 1 for the | CPT | used and related |
| 0510, clinic) | | ° code | | н | procedures |
| | | | | | |
| | | d | | | |
| | 44 HCPCS / RATE / HIPPS CODE | 45 SERV. DATE | 46 SERV. UNITS | 47 TOTAL CHARGES | 48 NON-COVERED CHARGES 49 |
| ® 60 mg | J0897-XX | MMDDYY | 60 | XX | XXX |
| | 96xxx | MMDDYY | 1 | XX | XXX |
| | | | | | |
| | for Medicare Part B o Related Administrati Determine appropris | on Procedure | 0 | | |
| OF | CREATION | DATE | TOTALS | | |
| | 52 REL | 53 ASG. 54 PRIOR PAYMENTS | 55 EST. AMOUNT | DUE 56 N | 21 |
| 511 | INFO | BEN. | : | 57 | |
| | | | | OTHE | B |
| | | | | PRV | |
| | D'S UNIQUE ID | 61.0 | ROUP NAME | | SURANCE GROUP NO. |
| nosis Codes: | S S SNIGOL ID | 010 | | 0211 | |
| | anacia | | | | |
| priate ICD-10-CM dia ed in patient's medio | ayiiusis cal record | | | | |
| | | NUMBER | 65.5 | EMPLOYER NAME | |
| 0(Age-related os athological fracture) | | | 031 | COLLINAME | |
| annological maclure) |) | | | | |
| | | | | | |
| | | | | | 68 |
| A D | | | 6 | 8 | |
| 70 PATIENT | 71 PPS | 72 | | | 73 |
| REASON DX | CODE | 72 ECI | a | U I | G |
| RE a. OTHER PROCE | DATE CODE | DATE | 6 ATTENDING NPI | | QUAL |
| | | - | AST | | FIRST |
| d. OTHER PROCE | DURE e. OTHER PROCEDU DATE CODE | DATE 7 | 7 OPERATING NPI | | QUAL |
| | | | | | FIRST |
| Box | 80. Remarks: | | | | QUAL |
| sumab) Paye | ers typically require provi | ders to list produ | ct name, rou | ute of | FIRST |
| 60 mg adm | inistration, total dosage, | | | | QUAL |
| | ng the billing period | | | | FIRST |
| APPROVED OMB NO | | | | | TO THIS BILL AND ARE MADE A PART HERE |



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

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 |
| | 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 |
| JW /JZ Modifier in Box 24D | 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*

| Devenue Orde | |
|--|--|
| Revenue Code: | N/A |
| | 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 |
| ICD-10-CM Code in Box 67: (Electronic Form: Loop 2300, HI01-2 [HI01-1 = BK]) | 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. |

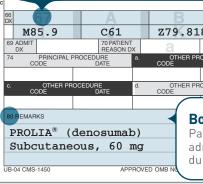
*The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for Prolia[®]. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and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

8 Please see Important Safety Information on the back cover.

Completing the CMS 1450 for Hospitals/Institutions – CTIBL



| Anytown Hospital 100 Main Street | 2 | 3a PAT. CNTL # b. MED. REC. # | | 6 STATEMENT COVERS PE | 4 TYPE OF BILL |
|--|--|--|--|---|----------------------------|
| Anytown, Anystate 01010 | | 5 FED. T | AX NO. | FROM THRO | DUGH |
| Pox 42. Revenue Codes: Product Medicare: Use revenue code 0636 (drugs in ther payers: Use revenue code 0250, ger required by a given payer) elated Administration Procedure Ise most appropriate revenue code or co vere performed (eg, 0510, clinic) | requiring detailed coding) neral pharmacy (or 0636, | Units: Indicate use of a syringe | eet, Any Service 60 units for 60 mg prefi of Prolia® 1 for the CF | lled Box 4 Char Repor charg used a | 47. Total |
| | | b | | | |
| 42 REV. CD. 43 DESCRIPTION 1 0636 PROLIA [®] 60 mg | 44 HCPCS / RATE / HIPPS CODE J0897-XX | 45 SERV. DATE 46 | 60 | TOTAL CHARGES 48 | 3 NON-COVERED CHARGES 49 |
| ² 0510 Clinic | 96XXX | MMDDYY | 1 | XXXXX | |
| 3 | | | | | |
| 0 | JW (discarded units) or following HCPCS code w Part B claims for drugs Related Administration F Determine appropriate | with a hyphen (e.g in single-use co Procedure | g. J0897-JZ) ntainers | for Medicare | |
| | | | | | |
| | OPENTION DA | Т | 55 EST. AMOUNT DUE | 56 NPI | |
| Box 67. Diagnosis Codes: | | 1 | 55 EST. AMOUNT DUE | 57 | |
| Indicate appropriate ICD-10-CM dia medical record | agnosis code as reflected in p | patient's | | OTHER | |
| | | | | PRV ID | |
| Example: M85.9 (disorder of bone of | lensity and structure, unspec | cified) | NAME | 62 INSURANCE GF | OUP NO. |
| | | -+-+-) | | | |
| Example secondary diagnosis: C61 | (matignant neoptasm of pros | | | | |
| Example additional diagnosis code: | | t] use of | 65 EMPL | OYER NAME | |
| other agents affecting estrogen rec | ceptors and estrogen levels) | | | | |
| c | | | | | |
| | C D | EF | | G H | 68 |
| M85.9 C61 Z79.818 | 71 PPS | N C | | P Q | 73 |
| DX REASON DX C | C CODE | 72 ECI 2 75 76 ATTE | | QUA | |
| | | LAST | | FIRST | |
| c. OTHER PROCEDURE d. OTHER PROCE CODE DATE d. CODE | EDURE e. OTHER PROCEDURE DATE CODE DATE | 77 OPE | RATING NPI | QUA | L |
| | · · · · | | | FIRST | |
| | c 80. Remarks: | | | QUA of FIRST | |
| | ers typically require provider ninistration, total dosage, and | | | | L |
| | ing the billing period | | ior the unit | s used First | <u> </u> |
| UB-04 CMS-1450 APPROVED OMB N | 5 51 | | | TO THIS BILL | AND ARE MADE A PART HEREOF |



M80.0___

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

| Age-related osteoporosis with current pathological fracture | |
|---|--|
| [laterality] [anatomic site] [encounter type]* | |

| | Encounter Type [†] | | | | | |
|---------------------------------|-----------------------------------|---|---|--|--|--------------------------------|
| Anatomic Site and Laterality | 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 HUMERUS | M80.019A | M80.019D | M80.019G | M80.019K | M80.019P | M80.019S |
| 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.

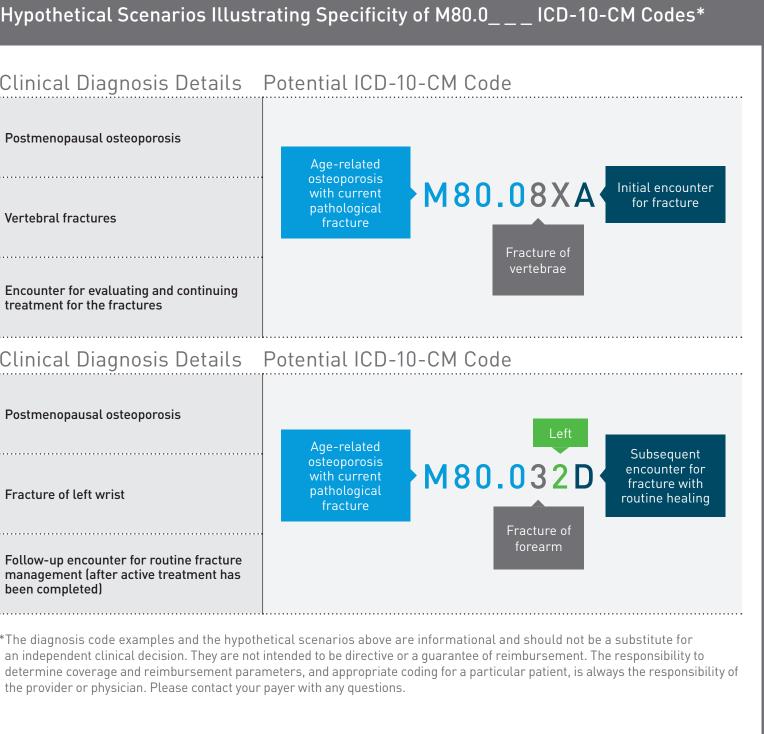
[‡]Osteoporotic fracture of femur is the approximate synonym of osteoporotic fracture of the hip.

Please see Important Safety Information on the back cover. 10

| Hypothetical Scenarios | Π |
|------------------------|---|
|------------------------|---|

| Clinical Diagnosis Detai |
|---|
| Postmenopausal osteoporosis |
| Vertebral fractures |
| Encounter for evaluating and continuin treatment for the fractures |
| Clinical Diagnosis Detai |
| Postmenopausal osteoporosis |
| Fracture of left wrist |
| Follow-up encounter for routine fractu management (after active treatment h been completed) |
| *The diagnosis code examples and the an independent clinical decision. They a |

*Tł the provider or physician. Please contact your payer with any questions.





ICD-10-CM CODE EXAMPLES – OSTEOPOROSIS

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

Important Safety Information

VIEW 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.

V 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®
- **Whypersensitivity:** 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®.
- 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

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

VATY Atypical Femoral Fractures: Atypical low-energy, or low trauma ractures 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,



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CODE EXAMPLES

Steonecrosis of the Jaw (ONJ): ONJ, which can occur spontaneously, of ONJ may increase with duration of exposure to Prolia®

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.

- **Verse 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.
- **Wusculoskeletal Pain:** Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking Prolia® onsider 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.
- **Variable Werse 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.

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



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 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.

AMGEN[®] Support⁺ Call Amgen[®] SupportPlus at 1-866-264-2778 Monday - Friday, 9:00 am – 8:00 pm ET. Visit AmgenSupportPlus.com to learn how Amgen can help.

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.





Prolia[®] (denosumab) Coding Information

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| 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 <i>without</i> 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) |
| A drainistration and | Drafaggianal Convige Coding Information* |

Administration and Professional Service Coding Information*

| Coding Information in Box 24D: | Healthcare providers should consult the payer or Medicare contractor to determine the code most | |
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| (Electronic Form: Loop 2400, | appropriate for administration. It is the provider's responsibility to ensure that codes used are | |
| SV1, 01-2] | 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.

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Prolia[®] (denosumab) Coding Information

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| 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 | navers other than traditional fee-for-service Medicare may vary: providers should check with their specific plans about |

*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*

| 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) M80.0_ (Age-related osteoporosis with current pathologic fracture) M80.8_ (Other osteoporosis with current pathological fracture) |
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| Professional Service Coding Information* |
| 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). 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 |
| 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. |
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*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.

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| commercial payers), | | d | enosumab | , 1 mg) | | | | | | | | PHYSICIAN OR SUPPLIER INFORMATIO |
| enter NDC for Prolia® | | | W/JZ Disc | ard Modif | ier | | | | | NPI | | |
| in shaded portion of | SSN | EIN | W (discard | | | no disc | arded | 3. TOTAL CHA | | . AMOUNT PA | D 30. Rsvd for NUCC | , Use |
| Item 24A above the | R SUPPLIE | | inits) modi | | | | | | OVIDER INFO 8 | | | |
| date of service. Check with the payer to | EDENTIALS he reverse | | ox for Med | | | | | p. DICLING PH | | |) | |
| determine the proper | part thereof | | n single-us | | | | - | | | | | |
| format for NDC | | | Related Adn | ninistratio | n Proc | edure | | | | | | |
| reporting | DATE | | etermine a | | | | | N | Pl b. | | | \rightarrow |
| NOCO INSTRUCTION MANUAL | / | | dministrat | | | | | A | PPROVED C | DMB-0938-* | 197 FORM 1500 (02 | 2-12) |
| | | \ | | - | | | | 1 | | | | |



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 |
| | 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 |
| JW /JZ Modifier in Box 24D | 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) |
| | ts 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 <i>with</i> 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 <i>without</i> 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 fracture: Z79.52 [Long-term [current] use of systemic steroids] |
| Administration Cod | ing Information* |
| Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201) | Appropriate revenue code for the cost center in which the service is performed. |

| | appropriate for administration of Prolia® |
|--|---|
| Coding Information in Box 43: | Determine appropriate product administration CPT code |
| (Electronic Form: Not required by Medicare) | • 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.

Completing the CMS 1450 for Hospital/Institutions – Osteoporosis

| Anytown Hospital | 2 | 3a PAT. CNTL # b. MED. REC. # | | 4 TYPE OF BILL |
|--|---|---|--------------------------------------|--|
| Anytown, Anystate 01010 | | 5 FED. TAX NO | 6 STATEM FROM | ENT COVERS PERIOD 7 THROUGH |
| Cmith Tam | | 122 Main Street | | Anustato 12245 |
| Box 42. Revenue Codes: Product Medicare: Use revenue code 0636 (drug Other payers: Use revenue code 0250, g if required by a given payer) Related Administration Procedure Use most appropriate revenue code or o were performed (eg, 0510, clinic) | s requiring detailed coding) eneral pharmacy (or 0636, | Box 46. Se Units: Indicate 60 | units for mg prefilled Prolia® | Anystate 12345 |
| 42 REV. CD. 43 DESCRIPTION | 44 HCPCS / RATE / HIPPS CODE | d : : : : : : : : : : : : : : : : : : : | JNITS 47 TOTAL CHARG | GES 48 NON-COVERED CHARGES 49 |
| 1 0636 PROLIA [®] 60 mg | J0897-XX | MMDDYY 60 | ž | |
| ² 0510 Clinic | 96XXX | MMDDYY 1 | ž | 2 |
| 10 11 11 11 12 11 13 11 14 11 15 11 16 11 17 11 18 11 19 11 10 11 11 11 12 11 13 11 14 11 15 11 16 11 17 11 18 11 19 11 10 11 11 11 12 11 13 11 14 11 15 11 16 11 17 11 18 11 19 11 10 11 11 11 12 11 13 11 14 11 15 11 16 11 17 11 18 11 19 11 19 11 10 11 11 11 12 | required following HCF for Medicare Part B cla Related Administration Determine appropriat | aims for drugs in single Procedure e product administrat | e-use containers | |
| 23 PAGE OF | 51 HEALTH PLAN ID | | | 23 |
| A SO PAYER NAME | | BEN. 54 PRIOR PAYMENTS 55 ES | 51. AMOUNT DUE 56 | 6 NPI |
| в | | | 0 | THER |
| c 58 | D'S UNIQUE ID | 61 GROUP NAME | | RV ID C |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM code as reflected in patient's me Example: M80.0(Age-related with current pathological fractur | diagnosis dical record. osteoporosis CUMENT CONTROL NUM | /BER | 65 EMPLOYER NAME | A B C A B C C C C C C |
| Bit A B M80.0XXX J K 69 ADMIT 70 PATIENT REASON DX A 74 PRINCIPAL PROCEDURE ODE CODE c. OTHER PROCEDURE CODE CODE c. OTHER PROCEDURE CODE d. | DATE CODE DA | LAST | | 68 68 73 0UAL FIRST 0UAL 0UAL 0UAL |
| BO BEMARKS PROLIA [®] (denosumab) Subcutaneous, 60 mg | DATE CODE DATE Dyers typically require provide ministration, total dosage, and pring the billing period | ers to list product nam | ne, route of | FIRST QUAL FIRST GUAL FIRST TO THIS BILL AND ARE MADE A PART HEREOF. |



Prolia® (denosumab) Coding Information

| • | · |
|---|---|
| Revenue Code in Box 42: | Medicare: 0636 (drugs requiring detailed coding) |
| (Electronic Form: Loop 2400, SV201) | Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer |
| Or dia a la francestica in Dev (/ | HCPCS code (J-code): J0897 (subcutaneous injection, denosumab, 1 mg) |
| Coding Information in Box 44: | Select the appropriate NDC from the following as seen on the product carton: |
| (Electronic Form: Loop 2400, SV202-2 [SV202-1 = HC/HP]) | NDC number: 55513-710-01 |
| 37202 2 [37202 1 = 110/111]) | NDC number: 55513-710-21 |
| | 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 |
| JW /JZ Modifier in Box 24D | 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 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) |
|---|--|
| | 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 |
| ICD-10-CM Code in Box 67: | |
| (Electronic Form: Loop 2300, HI01-2 [HI01-1 = BK]) | • Z79.818 [Long-term [current] use or other agents affecting estrogen receptors and estrogen levels] ⁺ |
| | • Z79.811 (Long-term [current] use of aromatase inhibitors) |
| | |
| | |
| | |
| | • 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.

Completing the CMS 1450 for Hospitals/Institutions – CTIBL



| ¹ Anytown Hospital | 2 | | PAT. TL # | | | | 4 TY OF | /PE BILL |
|---|--|---|---------------------------|----------------|---|--|-------------|-------------|
| 100 Main Street | | RE | ED. TAX NO. | 6 STATE | MENT COVERS | PERIOD | 7 | |
| Anytown, Anystate 01010 | | 5 F | ED. TAX NU. | FRO | IT N | IROUGH | | |
| | 1 | 23 Main St | reet, Z | Anytow | n, Any | rstate | e 1234 | 15 |
| x 42. Revenue Codes: | | cq | | | d 29 ACDT | 30 | е | |
| oduct | | | 46. Servio | ce | 8 STATE | | | |
| dicare: Use revenue code 0636 (drugs red | | | 5: ate 60 units | C C | IRE | . / D. T. | 41 | |
| <i>er payers:</i> Use revenue code 0250, gener equired by a given payer) | ral pharmacy (or 0636, | | f a 60 mg p | | | 47. To rges: | tal | |
| | | | ge of Prolia | | s Rep | ort appi | opriate | |
| ated Administration Procedure | | | ate 1 for the | • CPT | chai | ges for | product | |
| e most appropriate revenue code or cost re performed (eg, 0510, clinic) | center where services | b code | | COLL | | d and re edures: | lated | |
| (eg) (e.e., ee, | | c d | | | proc | | | _ |
| 42 REV. CD. 43 DESCRIPTION | 44 HCPCS / RATE / HIPPS CODE | 45 SERV. DATE | 46 SERV. UNITS | 47 TOTAL CH | RGES | 48 NON-COVE | RED CHARGES | 49 |
| 0636 PROLIA [®] 60 mg | J0897-XX | MMDDYY | 60 | | xxxxx | | | t |
| 0510 Clinic | 96XXX | MMDDYY | 1 | | XXXXX | | | |
| | | | | | | 5 | | ŀ |
| Box 43. Description: | Box 44. Product and | Product Prod | cedure Co | odes: | | | | T |
| ndicate the drug name and unit | Product | | | | | | | |
| f measure: Prolia® 60 mg | Use J0897 (subcutaned | - | enosumab, | , 1 mgJ | | | | |
| | JW/JZ Discard Modifie | - | | | | | | |
| | JW (discarded units) or following HCPCS code | | | | | | | |
| | Part B claims for drug | | | | culculc | | | |
| | Related Administration | Procedure | | | | | | |
| | Determine appropriate | | nistration C | CPT code | | | | |
| | | - | 1 | | | | | T |
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| | | | TOTALS | | | | | |
| (| OPENTION DA | Т | TOTALS | | 56 NPI | | | |
| Box 67. Diagnosis Codes: | | : | | INT DUE | 56 NPI 57 | | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn | | : | | | 57 OTHER | | | |
| Box 67. Diagnosis Codes: | | patient's | 55 EST. AMOU | | 57 OTHER PRV ID | CEOLENO | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn | nosis code as reflected in | patient's | | | 57 OTHER | GROUP NO. | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagr medical record Example: M85.9 (disorder of bone der | nosis code as reflected in nsity and structure, unspe | patient's | 55 EST. AMOU | INT DUE | 57 OTHER PRV ID | GROUP NO. | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record | nosis code as reflected in nsity and structure, unspe | patient's | 55 EST. AMOU | | 57 OTHER PRV ID 62 INSURANCE | GROUP NO. | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record Example: M85.9 (disorder of bone der Example secondary diagnosis: C61 (m Example additional diagnosis code: Z | nosis code as reflected in nsity and structure, unspe nalignant neoplasm of pro 79.818 (long-term [currer | patient's cified) | 55 EST. AMOU | 5 EMPLOYER NAM | 57 OTHER PRV ID 62 INSURANCE | GROUP NO. | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record Example: M85.9 (disorder of bone der Example secondary diagnosis: C61 (m | nosis code as reflected in nsity and structure, unspe nalignant neoplasm of pro 79.818 (long-term [currer | patient's cified) | 55 EST. AMOU | | 57 OTHER PRV ID 62 INSURANCE | GROUP NO. | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record Example: M85.9 (disorder of bone der Example secondary diagnosis: C61 (m Example additional diagnosis code: Z other agents affecting estrogen recep | nosis code as reflected in nsity and structure, unspe nalignant neoplasm of pro 79.818 (long-term [currer | patient's cified) | 55 EST. AMOU | | 57 OTHER PRV ID 62 INSURANCE | GROUP NO. | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record Example: M85.9 (disorder of bone der Example secondary diagnosis: C61 (m Example additional diagnosis code: Z other agents affecting estrogen recep | nosis code as reflected in nsity and structure, unspe nalignant neoplasm of pro 79.818 (long-term [currer | patient's cified) | 55 EST. AMOU | | 57 OTHER PRV ID 62 INSURANCE | GROUP NO. | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record Example: M85.9 (disorder of bone der Example secondary diagnosis: C61 (m Example additional diagnosis code: Z other agents affecting estrogen recep | nosis code as reflected in nsity and structure, unspe nalignant neoplasm of pro 79.818 (long-term [currer otors and estrogen levels) | patient's cified) state) st] use of | IOUP NAME | | 57 OTHER PRV ID 62 INSURANCE | | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record Example: M85.9 (disorder of bone der Example secondary diagnosis: C61 (m Example additional diagnosis code: Z other agents affecting estrogen recep | nosis code as reflected in nsity and structure, unspe nalignant neoplasm of pro 79.818 (long-term [currer otors and estrogen levels) | patient's cified) (state) (t] use of | 55 EST. AMOU | 5 EMPLOYER NAM | 57 OTHER PRV ID 62 INSURANCE | 68 | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record Example: M85.9 (disorder of bone der Example secondary diagnosis: C61 (m Example additional diagnosis code: Z other agents affecting estrogen recep M85.9 C61 Z79.818 EVANT REASON DX CODE DATE a CODE | nosis code as reflected in nsity and structure, unspe nalignant neoplasm of pro 79.818 (long-term [currer otors and estrogen levels) | patient's cified) state) it] use of E N E 75 76 76 76 | IOUP NAME | 5 EMPLOYER NAM | 57 OTHER PRV ID 62 INSURANCE | 68 73 IUAL | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record Example: M85.9 (disorder of bone der Example secondary diagnosis: C61 (m Example additional diagnosis code: Z other agents affecting estrogen recept M85.9 C61 Z79.818 PRINCIPAL PROCEDURE a OTHER PROCEDURE CODE OTHER PROCEDURE CODE OTHER PROCEDURE | nosis code as reflected in nsity and structure, unspe nalignant neoplasm of pro 79.818 (long-term [currer otors and estrogen levels) | patient's cified) state) it] use of E N E 75 76 76 76 | ISS EST. AMOU | 5 EMPLOYER NAM | 57 OTHER PRV ID 62 INSURANCE E E C C C C C C C C C C C C C | 68 73 UUAL 53 ST UUAL 1 | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record Example: M85.9 (disorder of bone der Example secondary diagnosis: C61 (m Example additional diagnosis code: Z other agents affecting estrogen recept M85.9 C61 Z79.818 BOX M85.9 C61 Z79.818 CODE DATE CODE ACCOUNT CODE CODE DATE CODE ACCOUNT CODE | nosis code as reflected in nsity and structure, unspe nalignant neoplasm of pro 79.818 (long-term [currer otors and estrogen levels) | patient's cified) state) it] use of E N E 75 76 76 76 | ST EST. AMOU | 5 EMPLOYER NAM | 57 OTHER PRV ID 62 INSURANCE 62 INSURANCE 62 INSURANCE 62 INSURANCE 62 INSURANCE 62 INSURANCE 62 INSURANCE 62 INSURANCE 63 INSURANCE 64 INSURANCE 65 INSURANCE 66 INSURANCE 66 INSURANCE 67 INSURANCE 67 INSURANCE 67 INSURANCE 67 INSURANCE 68 INSURANCE 69 INSURANCE 69 INSURANCE 69 INSURANCE 69 INSURANCE 60 | 68 73 104L 51 51 104L 51 51 | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record Example: M85.9 (disorder of bone der Example secondary diagnosis: C61 (m Example additional diagnosis code: Z other agents affecting estrogen recept M85.9 C61 Z79.818 PADMT REASON DX A PRINCIPAL PROCEDURE CODE CODE PROCEDURE CODE BORMARKS BOX 8 | nosis code as reflected in nsity and structure, unspe nalignant neoplasm of pro 79.818 (long-term [currer otors and estrogen levels) | patient's cified) istate) it] use of E 75 F 76 77 77 77 | ST OPERATING NF | 5 EMPLOYER NAM | 57 OTHER PRV ID 62 INSURANCE 62 INSURANCE 62 INSURANCE 62 INSURANCE 62 INSURANCE 62 INSURANCE 62 INSURANCE 62 INSURANCE 63 INSURANCE 64 INSURANCE 65 INSURANCE 66 INSURANCE 66 INSURANCE 67 INSURANCE 67 INSURANCE 67 INSURANCE 67 INSURANCE 68 INSURANCE 69 INSURANCE 69 INSURANCE 69 INSURANCE 69 INSURANCE 60 | 68 73 104L ↓ 5 5T 104L ↓ 5 5T 104L ↓ 5 | | |
| Box 67. Diagnosis Codes: Indicate appropriate ICD-10-CM diagn medical record Example: M85.9 (disorder of bone der Example secondary diagnosis: C61 (m Example additional diagnosis code: Z other agents affecting estrogen recep M85.9 C61 Z79.818 BO ADMIT 74 CODE CODITHER PROCEDURE CODE PROLIER PROCEDURE PROLIA® (denosumab) Box 8 Payers | nosis code as reflected in nsity and structure, unspe nalignant neoplasm of pro 79.818 (long-term [currer otors and estrogen levels) | patient's cified) istate) it] use of E T E T T T T T T T T T T T T T | SS EST. AMOU | 5 EMPLOYER NAM | 57 OTHER PRV ID 62 INSURANCE E E E E E E E E E E E E E E E E E E | 68 73 104L ↓ 5 5T 104L ↓ 5 5T 104L ↓ 5 | | |



M80.0___

Age-related osteoporosis with current pathological fracture

| llaterality | y] [ana | tomic s | ite] [en | counter | type]* |
|-------------|---------|---------|----------|---------|--------|
| | | | | | |

| | Encounter Type ⁺ | | | | | | | | |
|---------------------------------|-----------------------------------|---|---|--|--|----------|--|--|--|
| Anatomic Site and Laterality | 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 | | | |

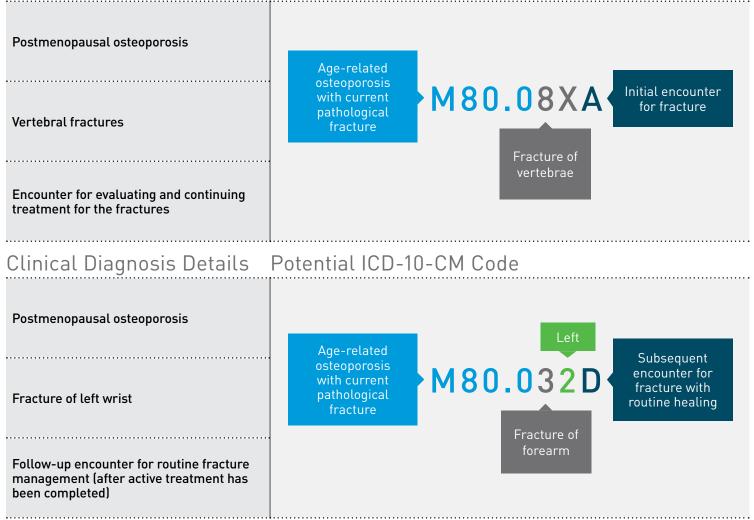
For other osteoporosis with or without current Pathological fracture refer to ICD-10 reference.

*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.

Clinical Diagnosis Details Potential ICD-10-CM Code



*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.



11

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

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.

W Multiple Vertebral Fractures (MVF) Following Discontinuation of

Prolia® Treatment: Following discontinuation of Prolia® treatment,



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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.

Wusculoskeletal 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 <u>Prescribing Information</u>, including Boxed Warning and <u>Medication Guide</u>.



ICD-10-CM CODE EXAMPLES