**Indications**

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

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

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

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

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

**Contraindications**

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

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

Please see Important Safety Information on the back.
Physician Office Billing Information – Osteoporosis

Prolia® (denosumab) Coding Information

Additional Claim Information

- **Electronic Form**: Loop 2300, or 2400, NTE, 02
- **Use of 60 mg prefilled syringe of Prolia® is reported as:**
  - **60 units**
  - The NDC number covers both injections

Coding Information in Box 24D:

- **HCPCS code (J-code)**: J0897 (injection, denosumab 1 mg)
- **NDC number**: 55513-0710-01

Number of Units in Box 24G:

- **(Electronic Form: Loop 2400, SV1, 03 = UN)**
- **Use of 60 mg prefilled syringe of Prolia® is reported as:**
  - **60 units**

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)

- **Please see page 10 for additional examples of patients with current osteoporotic fracture.

- **The following secondary diagnosis codes may be appropriate to describe patients for glucocorticoid-induced osteoporosis:**
  - **T38.0** (Age-related osteoporosis with current pathological fracture)
  - **T38.0X5** (Adverse effect of glucocorticoids and synthetic analogues, sequela)

- **The following primary diagnosis codes may be appropriate for patients without current osteoporotic fracture treated with Prolia®:**
  - **M81.0** (Age-related osteoporosis without current pathological fracture)
  - **M81.8** (Other osteoporosis without current pathological fracture)

- **The following secondary diagnosis codes may be appropriate to describe patients for glucocorticoid-induced osteoporosis:**
  - **T38.0X5** (Adverse effect of glucocorticoids and synthetic analogues, sequela)

Administration and Professional Service Coding Information

- **Coding Information in Box 24D:**
  - **(Electronic Form: Loop 2400, SV1, 01-2)**

- **The following code may be available to report administration of Prolia®:**
  - **96372** (therapeutic, prophylactic or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)

- **Relevant evaluation and management (E&M) code. Note when an E&M service is billed in addition to other professional services, the following modifier may be required to distinguish it as a separate service: -25 (significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service)**

- **Other codes may be appropriate on a payer-specific basis. It is the provider’s responsibility to ensure that codes used are consistent with payer policy and reflect service performed under such codes:**
  - **M81.0** (Age-related osteoporosis without current pathological fracture)

- **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 performed by the same physician on the same day of the procedure or other service)**

- **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 performed by the same physician on the same day of the procedure or other service)**

- **Other codes may be appropriate on a payer-specific basis. It is the provider’s responsibility to ensure that codes used are consistent with payer policy and reflect service performed under such codes:**
  - **M81.0** (Age-related osteoporosis without current pathological fracture)

- **Other codes may be appropriate on a payer-specific basis. It is the provider’s responsibility to ensure that codes used are consistent with payer policy and reflect service performed under such codes:**
  - **M81.8** (Other osteoporosis without current pathological fracture)

- **Other codes may be appropriate on a payer-specific basis. It is the provider’s responsibility to ensure that codes used are consistent with payer policy and reflect service performed under such codes:**
  - **T38.0X5** (Adverse effect of glucocorticoids and synthetic analogues, sequela)

- **Other codes may be appropriate on a payer-specific basis. It is the provider’s responsibility to ensure that codes used are consistent with payer policy and reflect service performed under such codes:**
  - **T38.0X5** (Adverse effect of glucocorticoids and synthetic analogues, sequela)

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

† According to the ICD-10-CM Official Guidelines for Coding and Reporting, M81.0 code is for use with patients with osteoporosis who do not currently have a pathologic fracture due to the osteoporosis, even if they have had a fracture in the past. For patients with a history of osteoporotic fractures, status code Z87.310 (personal history of [healed] osteoporosis fracture) should follow the code from the M81 category.

Please see Important Safety Information on the back.
Diagnosis/Condition Coding Information

Prolia® (denosumab) Coding Information

Additional Claim Information

[Box 19: Additional Claim Information]

- Prolia® (denosumab) 60 mg
- HCPCS code (J-code): J0897 (Injection, denosumab 1 mg)
- NDC number: 55513-0710-01

Number of Units

[Box 24G: Number of Units]

- Use of a 60 mg prefilled syringe of Prolia® is reported as:
- 60 units

Coding Information

[CPT code example: 96372 (Therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous)]

Considerations:

- The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include cancer treatment-induced bone loss (CTIBL) for use of a 60 mg prefilled syringe of Prolia®. Other codes may be appropriate given internal system guidelines, payer requirements, 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.
- Use of a 60 mg prefilled syringe of Prolia® is reported as:
- 60 units
- Diagnosis code M85.9 may apply for osteopenia.

Diagnosis/Condition Coding Information*

ICD-10-CM Code

[Box 21: Diagnosis or Nature of Illness]

- Cancer Diagnosis:
  - C61 (Malignant neoplasm of prostate)
  - Z79.818 (Use of Androgen Deprivation or Aromatase Inhibitor Therapy)
  - 279.816 (long-term [current] use of other agents affecting estrogen receptors and estrogen levels)
  - 279.819 (other long-term [current] drug therapy)
  - Other Risk Factors for Fracture:
    - M85.9 (disorder of bone density and structure, unspecified)

Coding Information

[Box 24C: Coding Information]

- The following code may be available to report administration of Prolia®. Other codes may be appropriate on a payer-specific basis. It is the provider’s responsibility to ensure that codes used are consistent with payer policy and reflect service performed under such codes:
  - 96372 (therapeutic, prophylactic or diagnostic injection [specify substance or drug]; subcutaneous, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous, or intramuscular)

Additional Claim Information

[Box 19: Additional Claim Information]

- 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 only allow for other levels when Modifier 25 is billed.

Completing the CMS 1500 for Physician Offices – CTIBL

| Box 19. Additional Claim Information: | Indicate Prolia® (denosumab) 60 mg |
| Box 20. Services, or Supplies: | Indicate 60 units for use of a 60 mg prefilled syringe of Prolia® |
| Box 21. Diagnosis or Nature of Illness or Injury: | Indicate appropriate ICD diagnosis code as reflected in the patient’s medical record (ICD-10 code example: M81.0 [Age-related osteoporosis without current pathological fracture]) |
| Box 24B. Diagnosis Code: | Specify diagnosis from Box 21 relating to each HCPCS or CPT code in Box 24C |
| Box 24D. Days or Units: | Indicate 1 for the CPT code |

* The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include cancer treatment-induced bone loss (CTIBL) for use of a 60 mg prefilled syringe of Prolia®. Other codes may be appropriate given internal system guidelines, payer requirements, and the services rendered.

* Code M85.9 may apply for osteopenia.
### Prolia® (denosumab) Coding Information

**Revenue Code in Box 42:**
- Medicare: 0636 (drugs requiring detailed coding)
- Other Payors: 0250, general pharmacy, or 0636, if required by a given payer

**Coding Information in Box 44:**
- HCPCS code (J-code): J0897 (subcutaneous injection, denosumab, 1 mg)
- NDC number: 55513-0710-01

**Service Units in Box 46:**
- 60 units (Prolia dose is 60 mg, per label)

### Diagnosis/Condition Coding Information*

**Revenue Code:**
N/A

**ICD-10-CM Code in Box 47:**
- M81.8 (Other osteoporosis without current pathological fracture)

**ICD-10-CM Code in Box 46:**
- M81.8 (Other osteoporosis without current pathological fracture)

**ICD-10-CM Code in Box 45:**
- M81.8 (Other osteoporosis without current pathological fracture)

**ICD-10-CM Code in Box 46:**
- M81.8 (Other osteoporosis without current pathological fracture)

**ICD-10-CM Code in Box 45:**
- M81.8 (Other osteoporosis without current pathological fracture)

### Administration Coding Information*

**Revenue Code in Box 42:**
- 96372 (therapeutic, prophylactic or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)

**Coding Information in Box 40:**
- 96372 (therapeutic, prophylactic or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)

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

**Box 42. Revenue Codes:**
- Product: Use revenue code 0636 (drugs requiring detailed coding)
- Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer)

**Box 43. Description:**
- Indicate the drug name and unit of measure: Prolia® 60 mg

**Box 44. Service Units:**
- Indicate 60 units for use of a 60 mg prefilled syringe of Prolia®

**Box 44. Product and Procedure Codes:**
- Use J0897 (subcutaneous injection, denosumab, 1 mg)

**Related Administration Procedure**
Use CPT code representing procedure performed, such as 93772, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

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

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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 FSA-approved indicators for Prolia®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

† According to the ICD-10-CM Official Guidelines for Coding and Reporting, M81 code is for use with patients with osteoporosis who do not currently have a pathologic fracture due to the osteoporosis, even if they have had a fracture in the past. For patients with a history of osteoporosis fractures, status code M80.0 (age-related osteoporosis without current pathological fracture) should follow the code from the M81 category.

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6 Please see Important Safety Information on the back.
### Prolija® (denosumab) Coding Information

<table>
<thead>
<tr>
<th>Revenue Code in Box 42</th>
<th>(Electronic Form: Loop 2600, SV001)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>Coding requirements for men receiving androgen deprivation therapy for nonmetastatic prostate cancer or women receiving adjuvant aromatase inhibitor therapy for breast cancer will vary from payer to payer. Sample factors appear below.</td>
</tr>
<tr>
<td><strong>Revenue Code</strong></td>
<td><strong>Box 42. Revenue Codes:</strong></td>
</tr>
<tr>
<td><strong>ICD-10-CM Code</strong></td>
<td><strong>Product</strong></td>
</tr>
<tr>
<td><strong>Cancer Diagnosis:</strong></td>
<td><strong>Prolija® 60 mg</strong></td>
</tr>
<tr>
<td><strong>Car1</strong> Intraorally neoplasms of prostate?</td>
<td><strong>0636</strong></td>
</tr>
<tr>
<td><strong>Use of Androgen Deprivation or Aromatase Inhibitor Therapy:</strong></td>
<td><strong>0636</strong></td>
</tr>
<tr>
<td><strong>279.81E</strong> (long-term [current]; use of other agents affecting estrogen receptors and estrogen levels)** OR</td>
<td><strong>0636</strong></td>
</tr>
<tr>
<td><strong>279.89Y</strong> (other long-term [current] drug therapy)?</td>
<td><strong>0636</strong></td>
</tr>
<tr>
<td><strong>Note Risk Factors for Fractures:</strong></td>
<td><strong>0636</strong></td>
</tr>
<tr>
<td><strong>MBS.V disorder of bone density and structure, unspecified</strong></td>
<td><strong>0636</strong></td>
</tr>
<tr>
<td>Appropriate revenue code for the cost center in which the service is performed.</td>
<td></td>
</tr>
</tbody>
</table>

### Administration Coding Information

<table>
<thead>
<tr>
<th>Revenue Code in Box 42</th>
<th>(Electronic Form: Loop 2600, SV001)</th>
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<tr>
<td><strong>Revenue Code</strong></td>
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<td><strong>ICD-10-CM Code</strong></td>
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<td><strong>279.89Y</strong> (other long-term [current] drug therapy)?</td>
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</tr>
<tr>
<td><strong>Note Risk Factors for Fractures:</strong></td>
<td><strong>0636</strong></td>
</tr>
<tr>
<td><strong>MBS.V disorder of bone density and structure, unspecified</strong></td>
<td><strong>0636</strong></td>
</tr>
</tbody>
</table>

### Considerations:

The following codes may be available to report administration of Prolija®. Other codes may be appropriate on a payer-specific basis. It is the provider’s responsibility to ensure that codes used are consistent with payer policy and reflect service performed under such codes:

- **94372** (therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular?)
- **Relevant evaluation and management (E&M) code.** Note when an E&M service is billed in addition to other professional services, the following modifier may be required to distinguish it as a separate service: .25 (significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service). Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same service. Medicare uses and related charges:
- Medicare: 0636 (drugs requiring detailed coding) OR
- Other payers: 0636 (general pharmacy) OR 0636, if required by a given payer

### Completing the CMS 1450 for Hospitals/Institutions – CTIBL

<table>
<thead>
<tr>
<th>Box 42. Revenue Codes:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product</strong></td>
</tr>
<tr>
<td><strong>Use revenue code 0636 (drugs requiring detailed coding)</strong></td>
</tr>
<tr>
<td><strong>Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer)</strong></td>
</tr>
</tbody>
</table>

### Related Administration Procedure

Use most appropriate revenue code or cost center where services were performed (eg, 0910, clinic)

### Box 63. Description:

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

### Box 67. Diagnosis Codes:

- **Example: 028.10-CM diagnosis code as reflected in patient’s medical record**
- **Example: MBS.V (disorder of bone density and structure, unspecified)**
- **Example secondary diagnosis: C61 (malignant neoplasm of prostate)**
- **Example additional diagnosis code: 279.818 (long-term [current] use of other agents affecting estrogen receptors and estrogen levels)**

### Box 60. Remarks:

Use most appropriate revenue code or cost center wherever services were performed (eg, 0910, clinic)

### Other payers:

- Use revenue code 0250, general pharmacy (or 0636, if required by a given payer)
- Use revenue code 0636 (drugs requiring detailed coding)
- Use revenue code 0636 (drugs requiring detailed coding)

### Box 44. Service Units: [Note: Use J0897 (subcutaneous injection, denosumab, 1 mg) for use of a 0.6 mg prefilled syringe of Prolija®]

- **Revenue Code: J0897**
- **Units: 1 x 0.6 mg syringe**

### Related Administration Procedure

Document product administration with appropriate CPT code Example: 96372 (therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)

- **Prolija® 60 mg**

**Please see Important Safety Information on the back.**
### Hypothetical Clinical Scenarios Illustrating Specificity of M80.0__ICD-10-CM Codes

#### Clinical Diagnosis Details | Potential ICD-10-CM Code
---|---
Postmenopausal osteoporosis | M80.08XA
Vertebral fractures | M80.08XG
Fracture of vertebrae | M80.08XK
Fracture of left wrist | M80.032D
Fracture of forearm | M80.052X

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#### References:

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#### See the next page for hypothetical scenarios illustrating specificity of these M80.0__ICD-10-CM codes.

The diagnosis codes examples above and the hypothetical scenarios on back of the insert are international 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.

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* 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 side 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 subsection in the Tabular List, are to be used for subsequent encounters for treatment of problems associated with healing, such as malunions, nonunions, and sequelae. 

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10 Please see Important Safety Information on the back.

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Important Safety Information

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

- Hypercalciemia: Clinically significant hypercalcemia including anaphylaxis has been reported with Prolia®. Symptoms have included, hypertension, dyspnea, throat tightness, facial and upper arm edema, pruritus, and urticaria. If an anaphylactic or other clinically significant allergy reaction occurs, initiate appropriate therapy and discontinue further use of Prolia®.

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

- Hypocalcemia: Hypocalcemia may worsen with the use of Prolia®, especially in patients with severe renal impairment. In patients predisposed to hyperparathyroidism and disturbances of mineral metabolism including treatment with other calcium-lowering drugs, clinical monitoring of calcium and mineral levels is highly recommended within 14 days of Prolia® injection. Concomitant use of calcitriol or calcitriol-like drugs should be closely monitored. Adequately supplement all patients with calcium and vitamin D.

- Osteonecrosis of the Jaw (ONJ): which can occur spontaneously, is generally associated with both alcohol and/or 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 medical conditions. 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 are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ 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 should guide the management plan of each patient.

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

- During Prolia® treatment, patients should be advised to report any unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be evaluated to rule out an asymptomatic tumor fracture. Interruption of Prolia® therapy should be considered, pending a radiologic/clinical assessment of the fracture.

- Multiple Vertebroplast Fractures: Malignant or benign vertebral fractures have occurred, including the risk of multiple vertebral fractures. New vertebral fractures occurred as early as 7 months (average length 17 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® therapy is discontinued, consider transitioning to an alternative anastrazole therapy.

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