PROLIA®
CODING AND BILLING
INFORMATION GUIDE

For physician offices using the CMS 1500

For hospitals/institutions using the CMS 1450

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

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

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

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

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

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

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

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

Please see Important Safety Information on the back.
**Prolia® (denosumab) Coding Information**

**Additional Claim Information in Box 19:**
(Electronic Form: Loop 2300, SV1, 01-2)

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

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

- Use of a 60 mg prefilled syringe of Prolia® is reported as:
  - 60 units
- The NDC number covers both injections

**Number of Units in Box 24G:**
(Electronic Form: Loop 2400, SV1, 04 [03 = UN])

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

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

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

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

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

**Box 24D. Procedures, Services, or Supplies:**
Indicate 1 for the CPT code

**Additional Claim Information in Box 19:**
(Shipped Form: Loop 2300, SV1, 01-2)

- **Prolia® (denosumab) 60 mg**
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Indicate appropriate ICD diagnosis code as reflected in the patient’s medical record. ICD-10-CM code example: M81.0 (Age-related osteoporosis without current pathological fracture)

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

**Box 24D. Procedures, Services, or Supplies:**
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 FDA-approved indications for Prolia®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

* According to the ICD-10-CM Official Guidelines for Coding and Reporting, M81 code is for use with patients with osteoporosis who do not currently have a pathological 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 S87.310 (personal history of healed osteoporosis fracture) should follow the code from the M81 category.”
Prolia® (denosumab) Coding Information

**Additional Claim Information in Box 19:**
- Prolia® (denosumab) 60 mg
- HCPCS code (J-code): J0897 (injection, denosumab 1 mg)
- NDC number: 55513-0710-01

**Coding Information in Box 24D:**
- Use of a 60 mg prefilled syringe of Prolia® is reported as:
  - 60 units

**Number of Units in Box 24G:**
- Use of a 60 mg prefilled syringe of Prolia® is reported as:
  - 60 units

**Diagnosis/Condition Coding Information**

**ICD-10-CM Code in Box 21:**

**Cancer Diagnosis:**
- C61 (malignant neoplasm of prostate)
- Use of Androgen Deprivation or Aromatase Inhibitor Therapy:
  - Z79.818 (long-term [current] use of other agents affecting estrogen receptors and estrogen levels)
  - Z79.899 (other long-term [current] drug therapy)
- Other Risk Factors for Fracture:
  - M85.9 (disorder of bone density and structure, unspecified)

**Administration and Professional Service Coding Information**

**Coding Information in Box 24D:**

**The following code may be available to report administration of Prolia®. Other codes may be appropriate on a payer-specific basis. It is the provider’s responsibility to ensure that codes used are consistent with payer policy and reflect service performed under such codes:**
- 96372 (therapeutic, prophylactic or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)
- Relevant evaluation and management (E&M) code. Note when an E&M service is billed in addition to other professional services, the following modifier may be required to distinguish it as a separate service: -.25 (significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service). Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when Modifier 25 is billed.

**Considerations:**

The Medicare Claims Processing Manual (CPM) and the American Medical Association (AMA) indicate that chemotherapy codes may be appropriate in the treatment of noncancer diagnosis or to substances, such as certain monoclonal antibody agents, and other biologic response modifiers. However, third-party payers or local carriers in the case of Medicare) make the determination for which specific codes are appropriate for billing. Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of Prolia®.

**PHYSICIAN OFFICE (CMS 1500) /endash.case CTIBL**
Diagnosis/Condition Coding Information*  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 Medicare. Coding Information in Box 43:

- HI01-2 [HI01-1 = BK] (Electronic Form: Loop 2300, ICD-10-CM Code in Box 67: SV205) (Electronic Form: Loop 2400, Service Units in Box 46: SV202-2 [SV202-1 = HC/HP])

- 60 units [Prolia dose is 60 mg, per label]

- Medicare: 0636 [drugs requiring detailed coding]†
- Other Payers: 0250, general pharmacy, OR 0636, if required by a given payer†

ICD-10-CM Code in Box 67: (Electronic Form: Loop 2300, HI01-2 [HI01-1 = BK]†)

- M81.8 Adverse effect of glucocorticoids and synthetic analogues, sequela
- M81.9 Other osteoporosis without current pathological fracture†
- M81.8 Other osteoporosis without current pathological fracture†
- M81.0 [Age-related osteoporosis without current pathological fracture]†
- M81.0 [Age-related osteoporosis without current pathological fracture]†

The following primary diagnosis codes may be appropriate for patients without current osteoporotic fracture treated with Prolia†:

- M81.0 [Age-related osteoporosis with current pathological fracture]†
- M81.8 [Other osteoporosis with current pathological fracture]†

The following secondary diagnosis codes may be appropriate to describe patients for glucocorticoid-induced osteoporosis:

- T38.03X Adverse effect of glucocorticoids and synthetic analogues, sequelae
- Due 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 Medicare. Coding Information in Box 43:

- HI01-2 [HI01-1 = BK] (Electronic Form: Loop 2300, ICD-10-CM Code in Box 67: SV205) (Electronic Form: Loop 2400, Service Units in Box 46: SV202-2 [SV202-1 = HC/HP])

- 60 units [Prolia dose is 60 mg, per label]

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The following secondary diagnosis codes may be appropriate to describe patients for glucocorticoid-induced osteoporosis:

- T38.03X Adverse effect of glucocorticoids and synthetic analogues, sequelae
Prolia\textsuperscript{\textregistered} (denosumab) Coding Information

**Revenue Code in Box 42:**
- Medicare: 0636 (drugs requiring detailed coding)\footnote{Diagnosis code 279.818 may be used for males receiving androgen deprivation therapy (e.g., leuprolide acetate or goserelin acetate) for prostate cancer.}
- Other Payors: Use J0897 (subcutaneous injection, denosumab, 1 mg)\footnote{CPT code 96372 (therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intra muscular) should be used for Prolia.}

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

**Service Units in Box 44:**
60 units (Prolia dose is 60 mg, per label)

**Revenue Code:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M53.9</td>
<td>Disorder of bone density and structure, unspecified</td>
</tr>
</tbody>
</table>

**Coding Requirements**
CPT codes may be more appropriate for services performed under such codes:
- 96372 (therapeutic, prophylactic or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)
- 717.818 (long-term [current] use of other agents affecting estrogen receptors and estrogen levels)
- M85.9 (disorder of bone density and structure, unspecified)

**Use Most Appropriate Revenue Code or Cost Center Where Services were Performed**

<table>
<thead>
<tr>
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**Considerations:**
- The following codes may be available to report administration of Prolia\textsuperscript{\textregistered}.
- "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:
- M85.9 (disorder of bone density and structure, unspecified)

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**HCPCS**
- For Medicare and Medicaid

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J0897</td>
<td>(subcutaneous injection, denosumab, 1 mg)</td>
</tr>
</tbody>
</table>

**Coding Information**

**ICD-10-CM Code in Box 67:**
- M63 (malignant neoplasm of prostate)
- Z79.818 (other long-term [current] drug therapy)
- Z79.818 (disorder of bone density and structure, unspecified)

**Administration Coding Information**

- Appropriate revenue code for the cost center in which the service was performed.

**Revenue Code in Box 42:**

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<th>Code</th>
<th>Description</th>
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**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 for local carriers in the case of Medicare) make the determination for which specific codes are appropriate for billing.

**Hospitalcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of Prolia\textsuperscript{\textregistered}.**

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<tr>
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**Example:**
- Example: M85.9 (disorder of bone density and structure, unspecified)
- Example secondary diagnosis: C61 (malignant neoplasm of prostate)
- Example: 96372 (therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)
- Example: 717.818 (long-term [current] use of other agents affecting estrogen receptors and estrogen levels)

**Box 43. Description:**
- Indicate the drug name and unit of measure: Prolia\textsuperscript{\textregistered} 60 mg

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

**Box 46. Service Units:**
- Indicate 60 units for use of a 60 mg prefilled syringe of Prolia\textsuperscript{\textregistered}
- Indicate 1 for the CPT code

**Box 47. Diagnosis Codes:**
- Indicate appropriate ICD-10-CM diagnosis code as reflected in patient’s medical record

**Box 48. Total Charges:**
- Report appropriate charges for product used and related procedures

**Box 49. Diagnosis/Condition Coding Information**
- Use most appropriate revenue code or cost center where services were performed (e.g., 0510, clinic)

**Box 50. Claim Type Information**
- Use 0510 Clinic

**Box 51. Hospital/Institution**
- Use 0510 Clinic

**Box 52. Hospital/Institution**
- Use 0510 Clinic

**Box 53. Hospital/Institution**
- Use 0510 Clinic

**Box 54. Hospital/Institution**
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**Box 55. Hospital/Institution**
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**Box 78. Hospital/Institution**
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**Box 79. Hospital/Institution**
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**Box 80. Hospital/Institution**
- Use 0510 Clinic

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Please see important Safety Information on the back.
<table>
<thead>
<tr>
<th>Anatomic Site and Laterality</th>
<th>M80.03XA</th>
<th>M80.032D</th>
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</thead>
<tbody>
<tr>
<td>SHOULDER</td>
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<td>(if required)</td>
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<td>Shoulder</td>
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<td>M80.032A</td>
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<td>M80.011A</td>
<td>M80.011D</td>
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<tr>
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<td>M80.012D</td>
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<tr>
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<td>(if required)</td>
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<tr>
<td>Right</td>
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<td>M80.021D</td>
</tr>
<tr>
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<td>M80.022A</td>
<td>M80.022D</td>
</tr>
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<td>M80.029D</td>
</tr>
<tr>
<td>FOREARM</td>
<td>(if required)</td>
<td>(if required)</td>
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<tr>
<td>Right</td>
<td>M80.031A</td>
<td>M80.031D</td>
</tr>
<tr>
<td>Left</td>
<td>M80.032A</td>
<td>M80.032D</td>
</tr>
<tr>
<td>Unspecified</td>
<td>M80.039A</td>
<td>M80.039D</td>
</tr>
<tr>
<td>HAND</td>
<td>(if required)</td>
<td>(if required)</td>
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<tr>
<td>Right</td>
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<td>M80.041D</td>
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<td>FEMUR</td>
<td>(if required)</td>
<td>(if required)</td>
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<tr>
<td>Right</td>
<td>M80.051A</td>
<td>M80.051D</td>
</tr>
<tr>
<td>Left</td>
<td>M80.052A</td>
<td>M80.052D</td>
</tr>
<tr>
<td>Unspecified</td>
<td>M80.059A</td>
<td>M80.059D</td>
</tr>
<tr>
<td>LOWER LEG</td>
<td>(if required)</td>
<td>(if required)</td>
</tr>
<tr>
<td>Right</td>
<td>M80.061A</td>
<td>M80.061D</td>
</tr>
<tr>
<td>Left</td>
<td>M80.062A</td>
<td>M80.062D</td>
</tr>
<tr>
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<td>M80.069A</td>
<td>M80.069D</td>
</tr>
<tr>
<td>ANKLE AND FOOT</td>
<td>(if required)</td>
<td>(if required)</td>
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<td>M80.071D</td>
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<tr>
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<td>M80.072A</td>
<td>M80.072D</td>
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<tr>
<td>VERTEBRAE</td>
<td>(if required)</td>
<td>(if required)</td>
</tr>
<tr>
<td>Right</td>
<td>M80.081A</td>
<td>M80.081D</td>
</tr>
<tr>
<td>Left</td>
<td>M80.082A</td>
<td>M80.082D</td>
</tr>
</tbody>
</table>

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

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

* 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 used to indicate that the fracture has completed active treatment. The other seven 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.

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

#### Clinical Diagnosis Details

<table>
<thead>
<tr>
<th>Potential ICD-10-CM Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>M80.08XA</td>
</tr>
<tr>
<td>Fracture of vertebrae</td>
</tr>
</tbody>
</table>

#### Potential ICD-10-CM Code

<table>
<thead>
<tr>
<th>Clinical Diagnosis Details</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Postmenopausal osteoporosis</td>
<td>M80.08XA</td>
</tr>
<tr>
<td>Vertebral fractures</td>
<td>Fracture of vertebrae</td>
</tr>
<tr>
<td>Encounter for evaluating and continuing treatment for the fractures</td>
<td>Fracture of vertebrae</td>
</tr>
</tbody>
</table>

#### Clinical Diagnosis Details

<table>
<thead>
<tr>
<th>Potential ICD-10-CM Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>M80.032D</td>
</tr>
<tr>
<td>Fracture of left wrist</td>
</tr>
</tbody>
</table>

#### Potential ICD-10-CM Code

<table>
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<tr>
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<tr>
<td>Fracture of left wrist</td>
<td>Fracture of forearm</td>
</tr>
<tr>
<td>Follow-up encounter for routine fracture management (after active treatment has been completed)</td>
<td>Fracture of forearm</td>
</tr>
</tbody>
</table>

### References:

Considerations for Complete Claim Submission

CORRECT AND COMPLETE PATIENT INFORMATION:
- Patient name
- ID number
- Health insurer name and/or group number
- Provider name
- National provider ID number
- Contact information

COLLECT PRODUCT AND BILLING INFORMATION:
- Correct HCPCS code and units
- Diagnosis code to the highest level of specificity
- Primary diagnosis code
- Identify appropriate administration code
- Determine prior authorization criteria
- If required
- Medicaid and commercial payers may need RIC reporting

SUPPLEMENTAL DOCUMENTATION CONSIDERATIONS (INCLUDING TEST RESULTS AND DATE AS APPROPRIATE):
- Original diagnostic t-score and/or FRAX predicted fracture risk
- Previous therapies
- Reason for discontinuations
- Calcium levels
- Prior osteoporosis-related fracture history
- Location of fracture (please provide ICD-10-UM code(s))
- Referring physician orders
- Risk factors for fracture

CONFIRM BILLING AND PAYOR REQUIREMENTS:
- Omit or include punctuation as required in submitted claims
- Follow required time frame for submission after rendering service

Important Safety Information
- **Contraindications:** Prolia® is contraindicated in patients with hypersensitivity to Prolia®. In the event of hypersensitivity, treatment with Prolia® must be discontinued prior to initiating Prolia®. Prolia® is contraindicated in women who are pregnant and in women who are breast-feeding. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment with Prolia®. Prolia® is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling and urticaria.

- **Same Active Ingredient:** Prolia® contains the same active ingredient (denosumab) found in XGEVA®. Patients receiving Prolia® should not receive XGEVA®.

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

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

- **Osteonecrosis of the Jaw (ONJ):** ONJ, which can occur spontaneously in generally associated with both systemic and 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, concomitant therapies (e.g., chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and/or immunocompromised disorders. Good oral hygiene practices should be maintained during treatment with Prolia®. The risk of ONJ may increase with duration of therapy with Prolia®. For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are considering 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 femur have been reported in patients receiving Prolia®. Causality has not been established as these fractures also occur in osteoporotic patients who have 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 inconspicuous 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, fractures may reoccur, including the risk of multiple vertebral fractures. New vertebral fractures occurred as early as 7 months (for average 14 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) in women with postmenopausal osteoporosis, serious infections leading to hospitalization were reported more frequently in the Prolia® group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear were more frequent in patients treated with Prolia®.

- Endocaritis was also reported more frequently in Prolia®-treated patients. The incidence of opportunistic infections and the overall incidence of infections were similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis. Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Prolia®, prescribers should assess the need for continued Prolia® therapy.

- **Dermatologic Adverse Reactions:** In the same clinical trial in women with postmenopausal osteoporosis, skin and nail adverse events such as dermatitis, acnaea and rashes occurred at a significantly higher rate with Prolia® compared to placebo. Most of these events were not specific to the injection site. Consider discontinuing Prolia® if severe symptoms develop.

- **Musculoskeletal Pain:** Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking Prolia®. Consider discontinuing use if severe symptoms develop.

- **Suppression of Bone Remodeling:** As evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the affect of long-term treatment are unknown. Monitor patients for these consequences, including ONJ, atypical fractures, and delayed fracture healing.

- **Adverse Reactions:** The most common adverse reactions (>1% and more common than placebo) in women with bone loss receiving ADT for prostate cancer were arthralgia, facial swelling, and urticaria. In patients with bone loss receiving ADT for prostate cancer or adenocarcinoma, arthralgia, facial swelling, and urticaria have also been reported in patients receiving Prolia®. Arthralgia, facial swelling, and urticaria have also been reported in patients treated with Prolia®. In clinical trials, arthralgia, facial swelling, and urticaria have also been reported in patients treated with Prolia®.

- **Allergic Reactions:** If an allergic reaction occurs, initiate appropriate therapy and discontinue further use of Prolia®.

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