PHYSICIAN OFFICE CODING AND BILLING INFORMATION SHEET FOR XGEVA®

Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.amgenassist360.com

Please see Important Safety Information on pages 10–11 and the accompanying XGEVA® full Prescribing Information.
XGEVA® is indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.

**Important Safety Information**

**XGEVA®** is contraindicated in patients with pre-existing hypocalcemia and clinically significant hypersensitivity to XGEVA®. XGEVA® can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Osteonecrosis of the jaw and atypical femoral fracture have been reported. Clinically significant hypercalcemia following treatment discontinuation in patients with Giant Cell Tumor of Bone and in patients with growing skeletons has been reported. Multiple vertebral fractures following discontinuation of treatment have been reported. XGEVA® can cause fetal harm.

Please see pages 10-11 for additional Important Safety Information.

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**PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR XGEVA®**

**XGEVA®**

**Coding Information**

- **HCP5/CPT**/**ICD-10-CM**

**Notes**

XGEVA® is supplied as a 120 mg dose; its NDC is 55513-0730-01.

**Administration**

- 96372, therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular; OR 76401, chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic

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 XGEVA®.

**Office Visit**

- Relevant Evaluation and Management (E&M) code*

See payer guidelines

**Diagnosis/Condition**

- Appropriate (ICD-10-CM code(s) for patient condition

**Example:**

- C79.51
  - Secondary malignant neoplasm of bone

Allowable diagnosis codes may vary by payer.

**PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR XGEVA®**

**The CMS 1500 for Physician Office**

Sample CMS 1500 Form — Physician Office Administration

**Important Note:** This sample form is intended as a reference for coding and billing for product and associated services. This form is not intended to be directive; the use of the recommended codes does not guarantee reimbursement.

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this section be considered a guarantee of coverage or reimbursement for any product or service.

**CPT** is a registered trademark of the American Medical Association.

**PHYSICIAN OFFICE /emdash.case BILLING INFORMATION SHEET FOR XGEVA®**

**ITEM CODING INFORMATION (HCP5/CPT*/ICD-10-CM)**

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**Diagnosis/Condition**

- Appropriate (ICD-10-CM code(s) for patient condition

**Example:**

- C79.51
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Allowable diagnosis codes may vary by payer.

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**IMPORTANT SAFETY INFORMATION**

XGEVA® is indicated in patients with pre-existing hypocalcemia and clinically significant hypersensitivity to XGEVA®. XGEVA® can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Osteonecrosis of the jaw and atypical femoral fracture have been reported. Clinically significant hypercalcemia following treatment discontinuation in patients with Giant Cell Tumor of Bone and in patients with growing skeletons has been reported. Multiple vertebral fractures following discontinuation of treatment have been reported. XGEVA® can cause fetal harm.

Please see pages 10-11 for additional Important Safety Information.

Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.amgenassist360.com

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**PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR XGEVA®**

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**Example:**

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**PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR XGEVA®**

**The CMS 1500 for Physician Office**

Sample CMS 1500 Form — Physician Office Administration

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**Diagnosis/Condition**

- Appropriate (ICD-10-CM code(s) for patient condition

**Example:**

- C79.51
  - Secondary malignant neoplasm of bone

Allowable diagnosis codes may vary by payer.

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**IMPORTANT SAFETY INFORMATION**

XGEVA® is indicated in patients with pre-existing hypocalcemia and clinically significant hypersensitivity to XGEVA®. XGEVA® can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Osteonecrosis of the jaw and atypical femoral fracture have been reported. Clinically significant hypercalcemia following treatment discontinuation in patients with Giant Cell Tumor of Bone and in patients with growing skeletons has been reported. Multiple vertebral fractures following discontinuation of treatment have been reported. XGEVA® can cause fetal harm.

Please see pages 10-11 for additional Important Safety Information.

Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.amgenassist360.com
XGEVA® is indicated for treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

**Important Safety Information**

XGEVA® is contraindicated in patients with pre-existing hypocalcemia and clinically significant hypercalcemia sensitivity to XGEVA®. XGEVA® can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Osteonecrosis of the jaw and atypical femoral fracture have been reported. Clinically significant hypercalcemia following treatment in patients with growing skeletons has been reported. Multiple vertebral fractures following treatment in patients with Giant Cell Tumor of Bone and in patients with growing skeletons has been reported.

Please see pages 10-11 for additional Important Safety Information.

Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.amgenassist360.com

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**PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR XGEVA®**

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<td>90977, SC injection, denosumab, 1 mg</td>
<td>XGEVA® is supplied as a 120 mg dose administered every 4 weeks with additional 120 mg doses on days 8 and 15 of the first month of therapy; its NDC is 55513-0730-01*</td>
</tr>
<tr>
<td>Administration</td>
<td>94372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular; OR 94661, chemotherapy administration, subcutaneous or intramuscular, non-hormonal antineoplastic</td>
<td>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 (i.e., 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 XGEVA®.</td>
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<td>Office visit</td>
<td>Relevant Evaluation and Management (E&amp;M) code**</td>
<td>See payer guidelines</td>
</tr>
<tr>
<td>Diagnosis/Condition</td>
<td>Appropriate ICD-10-CM code[s] for patient condition</td>
<td>Example: D48.0 Osteonecrosis of uncertain behavior of bone and articular cartilage Allowable diagnosis codes may vary by payer</td>
</tr>
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**The CMS 1500 for Physician Office**

Sample CMS 1500 Form — Physician Office Administration

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be the basis, the sole or recommended code does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.
XGEVA® is indicated for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

**Coding Information**

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**Administration**

96372, therapeutic/prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular; OR 96401, chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic

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 XGEVA®.

**Office Visit**

Relevant Evaluation and Management (E&M) code

See payer guidelines

**Diagnosis/Condition**

Appropriate ICD-10-CM code(s) for patient condition

**Example:**

E83.52

Hypercalcemia

For patients receiving treatment for hypercalcemia of malignancy, payers may also require to document the diagnosis code describing the malignancy, however, specific coding requirements may vary by payer.

For assistance with payer-specific requirements, please contact local payer or Amgen Assist 360® at 888-4ASSIST.

**Important Safety Information**

XGEVA® is contraindicated in patients with pre-existing hypocalcemia and clinically significant hypersensitivity to XGEVA®. XGEVA® can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Osteonecrosis of the jaw and atypical femoral fracture have been reported. Clinically significant hypercalcemia following treatment discontinuation in patients with Giant Cell Tumor of Bone and in patients with growing skeletons has been reported. Multiple vertebral fractures following discontinuation of treatment have been reported. XGEVA® can cause fetal harm.

Please see pages 10-11 for additional Important Safety Information.

Contact Amgen Assist 360® for reimbursement and access resources at 1-888-4ASSIST or www.amgenassist360.com

**The CMS 1500 for Physician Office Sample CMS 1500 Form — Physician Office Administration**

**HOSPITAL CODING AND BILLING INFORMATION SHEET FOR XGEVA**

**The CMS 1500 for Physician Office Sample CMS 1500 Form — Physician Office Administration**

**Health Insurance Claim Form**

**Health Insurance Claim Form**

**PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR XGEVA®**

**PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR XGEVA®**

**PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR XGEVA®**
XGEVA® is indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.

**Important Safety Information**

XGEVA® is contraindicated in patients with pre-existing hypocalcemia and clinically significant hypersensitivity to XGEVA®. XGEVA® can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Osteonecrosis of the jaw and atypical subtrochanteric and diaphyseal femoral fracture have been reported. Clinically significant hypercalcemia following treatment discontinuation in patients with Giant Cell Tumor of Bone and in patients with growing skeletons has been reported. Multiple vertebral fractures following discontinuation of treatment have been reported. XGEVA® can cause fetal harm. Please see pages 10-11 for additional Important Safety Information.

Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4ASSIST or www.amgenassist360.com

**Administration**

The Medicare Claims Processing Manual (EPM) and the American Medical Association (AMA) indicate that chemotherapy codes may be appropriate in the treatment of a noncancer diagnosis or to substances, such as certain monoclonal antibody agents, and other biologic response modifiers.4,2 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 XGEVA®.

**Drug Products with Same Active Ingredient**

XGEVA® is contraindicated in patients with known clinically significant hypersensitivity to XGEVA®, including hypersensitivity to denosumab. Patients receiving XGEVA® should not take Prolia® (denosumab).

**Osteonecrosis of the Jaw**

Patients receiving XGEVA® may experience osteonecrosis of the jaw (ONJ). In clinical trials in patients with cancer, the incidence of ONJ was higher with longer duration of exposure. Examples include erosion. Persistent pain or slow healing of the mouth or jaw after dental surgery may also be manifestations of osteomyelitis, osteitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration, or gingival hemorrhage. Healthcare providers should assess patients for signs and symptoms of ONJ. If ONJ is suspected, stop XGEVA® and refer the patient to a healthcare professional for evaluation and management.ONJ may be complicated by infectious complications such as osteomyelitis and sinus infection.

**An increased risk of hypocalcemia has been observed in clinical trials of patients with increasing renal dysfunction, most commonly with severe dysfunction (creatinine clearance less than 30 mL/minute and/or on dialysis), and with patients who have had substantial reductions in their calcium levels.**

Healthcare providers should warn patients that hypocalcemia may occur. Advise patients to contact a healthcare professional for symptoms of hypocalcemia.

**ONJ.** In clinical trials in patients with cancer, the incidence of ONJ was higher with longer duration of exposure. Patients presenting with an atypical femur fracture should also be assessed for incomplete femur fracture. Patients presenting with an atypical femur fracture should also be assessed for osteonecrosis of the jaw.

**(Hypocalcemia)**

In clinical trials of patients with increasing renal dysfunction, most commonly with severe dysfunction (creatinine clearance less than 30 mL/minute and/or on dialysis), and with patients who have had substantial reductions in their calcium levels, an increased risk of hypocalcemia has been observed. Hypocalcemia may also occur in patients with low baseline calcium levels at the start of XGEVA® therapy. Hypocalcemia may result in muscle cramps, tetany, and/or seizures. Patients with hypocalcemia should be treated appropriately.

**Hypocalcemia**

An increased risk of hypocalcemia has been observed in clinical trials of patients with increasing renal dysfunction, most commonly with severe dysfunction (creatinine clearance less than 30 mL/minute and/or on dialysis), and with patients who have had substantial reductions in their calcium levels. Hypocalcemia may also occur in patients with low baseline calcium levels at the start of XGEVA® therapy. Hypocalcemia may result in muscle cramps, tetany, and/or seizures. Patients with hypocalcemia should be treated appropriately.

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Healthcare providers should warn patients that hypocalcemia may occur. Advise patients to contact a healthcare professional for symptoms of hypocalcemia.

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**Hypocalcemia**

An increased risk of hypocalcemia has been observed in clinical trials of patients with increasing renal dysfunction, most commonly with severe dysfunction (creatinine clearance less than 30 mL/minute and/or on dialysis), and with patients who have had substantial reductions in their calcium levels. Hypocalcemia may also occur in patients with low baseline calcium levels at the start of XGEVA® therapy. Hypocalcemia may result in muscle cramps, tetany, and/or seizures. Patients with hypocalcemia should be treated appropriately.
Important Safety Information

Hypocalcemia
- Pre-existing hypocalcemia must be corrected prior to initiating therapy with XGEVA®. XGEVA® can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Monitor calcium levels, especially in the first weeks of initiating therapy, and administer calcium, magnesium, and vitamin D as necessary. Monitor levels more frequently when XGEVA® is administered with other drugs that can also lower calcium levels. Advise patients to contact a healthcare professional for symptoms of hypocalcemia.
- An increased risk of hypocalcemia has been observed in clinical trials of patients with increasing renal dysfunction, most commonly with severe dysfunction (creatinine clearance less than 30 mL/minute and/or on dialysis), and with inadequate/no calcium supplementation. Monitor calcium levels and calcium and vitamin D intake.

Hypersensitivity
- XGEVA® is contraindicated in patients with known clinically significant hypersensitivity to XGEVA®, including anaphylaxis that has been reported with use of XGEVA®. Reactions may include hypotension, dyspepsia, upper airway edema, lip swelling, rash, pruritus, and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue XGEVA® therapy permanently.

Drug Products with Same Active Ingredient
- Patients receiving XGEVA® should not take Prolia® (denosumab).

Osteonecrosis of the Jaw
- Osteonecrosis of the jaw (ONJ) has been reported in patients receiving XGEVA®, manifesting as jaw pain, osteomyelitis, ostelitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration, or gingival erosion. Persistent pain or slow healing of the mouth or jaw after dental surgery may also be manifestations of ONJ. In clinical trials in patients with cancer, the incidence of ONJ was higher with longer duration of exposure.
- Patients with a history of tooth extraction, poor oral hygiene, or use of a dental appliance are at a greater risk to develop ONJ. Other risk factors for the development of ONJ include immunosuppressive therapy, treatment with angiogenesis inhibitors, systemic corticosteroids, diabetes, and gingival infections.
- Perform an oral examination and appropriate preventive dentistry prior to the initiation of XGEVA® and periodically during XGEVA® therapy. Advise patients regarding oral hygiene practices. Avoid invasive dental procedures during treatment with XGEVA®. Consider temporarily interrupting XGEVA® therapy if an invasive dental procedure must be performed.
- Patients who are suspected of having or who develop ONJ while on XGEVA® should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery to treat ONJ may exacerbate the condition.

Atypical Subtrochanteric and Diaphyseal Femoral Fracture
- Atypical femoral fracture has been reported with XGEVA®. These fractures can occur anywhere in the femoral shaft from just below the lesser trochanter to above the supracondylar flare and are transverse or short oblique in orientation without evidence of comminution.
- Atypical femoral fractures most commonly occur with minimal or no trauma to the affected area. They may be bilateral and many patients report prodromal pain in the affected area, usually presenting as dull, aching thigh pain, weeks to months before a complete fracture occurs. A number of reports note that patients were also receiving treatment with glucocorticoids (e.g. prednisone) at the time of fracture. During XGEVA® 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 suspected of having an atypical fracture and should be evaluated to rule out an incomplete femur fracture. Patients presenting with an atypical femur fracture should also be assessed for symptoms and signs of fracture in the contralateral limb. Interruption of XGEVA® therapy should be considered, pending a risk/benefit assessment, on an individual basis.

Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone (GCTB) and in Patients with Growing Skeletons
- Clinically significant hypercalcemia requiring hospitalization and complicated by acute renal injury has been reported in XGEVA®-treated patients with GCTB and in patients with growing skeletons within one year of treatment discontinuation. Monitor patients for signs and symptoms of hypercalcemia after treatment discontinuation and treat appropriately.

Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation
- Multiple vertebral fractures (MVF) have been reported following discontinuation of treatment with denosumab. Patients at higher risk for MVF include those with risk factors for or a history of osteoporosis or prior fractures. When XGEVA® treatment is discontinued, evaluate the individual patient’s risk for vertebral fractures.

Embryo-Fetal Toxicity
- XGEVA® can cause fetal harm when administered to a pregnant woman. Based on findings in animals, XGEVA® is expected to result in adverse reproductive effects.
- Advise females of reproductive potential to use effective contraception during therapy, and for at least 5 months after the last dose of XGEVA®. Apprise the patient of the potential hazard to a fetus if XGEVA® is used during pregnancy or if the patient becomes pregnant while patients are exposed to XGEVA®.

Adverse Reactions
- The most common adverse reactions in patients receiving XGEVA® with bone metastasis from solid tumors were fatigue/asthenia, hypophosphatemia, and nausea. The most common adverse reactions resulting in discontinuation were osteonecrosis and hypocalcemia.
- For multiple myeloma patients receiving XGEVA®, the most common adverse reactions were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache. The most common serious adverse reaction was pneumonia. The most common adverse reaction resulting in discontinuation of XGEVA® was osteonecrosis of the jaw.
- The most common adverse reactions in patients receiving XGEVA® for giant cell tumor of bone were arthralgia, headache, nausea, back pain, fatigue, and pain in extremity. The most common serious adverse reactions were osteonecrosis of the jaw and osteomyelitis. The most common adverse reactions resulting in discontinuation of XGEVA® were osteonecrosis of the jaw and tooth abscess or tooth infection.
- The most common adverse reactions in patients receiving XGEVA® for hypercalcemia of malignancy were nausea, dyspepsia, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.

Please see accompanying Prescribing Information.
See How We Can Help Your Patients
Offering the tools, information, and support for Amgen products that make a difference for you and your patients

AMGEN REIMBURSEMENT SPECIALISTS
Connect with an Amgen Reimbursement Counselor or schedule a visit with a Field Reimbursement Specialist

PATIENT RESOURCE GUIDE
Find co-pay and reimbursement resources* for patients with different kinds of insurance, or no insurance at all

BENEFIT VERIFICATION
Submit, store, and retrieve benefit verifications for all your patients currently on an Amgen product

CALL 1-888-4ASSIST (888-427-7478)
Monday to Friday, 9:00 AM to 8:00 PM EST,
_OR VISIT AMGENASSIST360.COM

References