

XGEVA® is indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.

ITEM	CODING INFORMATION (HCPCS ¹ /CPT ^{®2} /ICD-10-CM ³)	NOTES
XGEVA®	J0897, SC injection, denosumab, 1 mg	XGEVA® is supplied as a 120 mg dose; its NDC is 55513-0730-01 ⁴
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. ^{2,5} 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

* Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.

† 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.⁵

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.

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**

PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR XGEVA®

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.

ITEM	CODING INFORMATION (HCPCS ¹ /CPT ² /ICD-10-CM ³)	NOTES
XGEVA®	J0897, SC injection, denosumab, 1 mg	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 ⁴
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. ^{2,5} 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: D48.0 Neoplasm of uncertain behavior of bone and articular cartilage Allowable diagnosis codes may vary by payer

* Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.

[†] 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.⁵

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.

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

PHYSICIAN OFFICE — BILLING INFORMATION SHEET FOR XGEVA®

XGEVA® is indicated for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

ITEM	CODING INFORMATION (HCPCS ¹ /CPT ² /ICD-10-CM ³)	NOTES
XGEVA®	J0897, subcutaneous (SC) injection, denosumab, 1 mg	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 ⁴
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. ^{2,5} 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.

* Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.

† 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.⁵

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.

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

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. Concomitant use of calcimimetics and other drugs that can lower calcium levels may worsen hypocalcemia risk and serum calcium should be closely monitored. 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, dyspnea, 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, osteitis, 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 serious adverse reaction was dyspnea. 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, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.

Please [click here](#) for the Prescribing Information.

XGEVA[®]
(denosumab) injection
120 mg/1.7 mL vial



Support, Simplified

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

* Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

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

References

1. Centers for Medicare and Medicaid Services. 2017 Table of Drugs. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2017-Table-of-Drugs.pdf>. Accessed October 19, 2017.
2. American Medical Association. Current Procedural Technology [CPT®] 2018 Professional Edition. Copyright 2017 American Medical Association. All rights reserved.
3. Centers for Medicare and Medicaid Services. 2018 ICD-10-CM Tabular List of Diseases and Injuries. 2017. <https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2018-ICD-10-Table-And-Index.zip>. Accessed October 19, 2017.
4. XGEVA® prescribing information, Amgen.
5. Centers for Medicare and Medicaid Services. Medicare Claims Processing Manual. Chapter 12 – Physicians/Nonphysician Practitioners. 2017. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf>. Accessed October 19, 2017.



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

© 2020 Amgen Inc. All rights reserved. USA-OCF-80944 03/20

XGEVA®
(denosumab) injection

120 mg/1.7 mL vial