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

ELECTRONIC MEDICAL RECORD/ PRACTICE MANAGEMENT SYSTEM TIP SHEET

This tool provides a few examples of queries on electronic medical records and/or practice management systems that may be helpful in identifying appropriate patients for XGEVA® (denosumab) and should not be used for coding or reimbursement.*

*These examples are not intended to be instructive with respect to clinical decision-making or billing and coding. Healthcare providers are solely responsible for clinical decisions and ensuring the accuracy and validity of all billing and claims. This is not a guarantee of coverage or reimbursement for any product or service.

Indication

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

Please see Important Safety Information on pages 6-7.

INFORMATION FOR PATIENTS WITH BONE METASTASES FROM SOLID TUMORS

PATIENT TYPES	SEARCH CRITERIA TO CONSIDER	HELPFUL SEARCH TIPS
Patients with undetected and untreated bone metastases from solid tumors	• Bone metastases from solid tumors detected based on chart review and further bone imaging	• ICD-10-CM codes may be used to identify patients with solid tumors; common examples include:[1] » C50.011 – C50.929 for breast cancer » C61 for prostate cancer » C34.00 – C34.92 for lung cancer
Patients with bone metastases from solid tumors who are currently treated with bone-targeting therapy	• ICD-10-CM code for bone metastases (C79.51)[1] AND • One of the following HCPCS codes for bone-targeting therapy within the past 4 weeks: » J3489[2] for zoledronic acid or » J2430[2] for pamidronate	• ICD-10-CM codes may be used to identify patients with solid tumors; common examples include:[1] » C50.011 – C50.929 for breast cancer » C61 for prostate cancer » C34.00 – C34.92 for lung cancer
Patients with bone metastases from solid tumors who are not currently treated with bone-targeting therapy and have evidence of a skeletal-related event (SRE)	• ICD-10-CM code for bone metastases (C79.51)[1] AND • None of the following HCPCS codes for bone-targeting therapy within the past 4 weeks: » J3489[2] for zoledronic acid and » J2430[2] for pamidronate and » J0897[2] for denosumab AND • Evidence of SRE: » ICD-10-CM code for pathologic fracture (M84.40XA – M84.68XS, M48.50XA – M48.58XS)[1] or history of fracture (Z87.311)[1] or » ICD-10-CM code for spinal cord compression (G95.9)[1] or » History of radiation to the bone, bone surgery, and/or hospitalization for SRE	• Establishing evidence of SRE and confirming lack of therapy may require patient chart review • These patients may include those who were previously treated with bone-targeting therapy and those who are treatment-naïve
Patients with bone metastases from solid tumors who are not currently treated with bone-targeting therapy, have evidence of an SRE, and have reduced renal function	• ICD-10-CM code for bone metastases (C79.51)[1] AND • None of the following HCPCS codes for bone-targeting therapy within the past 4 weeks: » J3489[2] for zoledronic acid and » J2430[2] for pamidronate and » J0897[2] for denosumab AND • Evidence of SRE: » ICD-10-CM code for pathologic fracture (M84.40XA – M84.68XS, M48.50XA – M48.58XS)[1] or history of fracture (Z87.311)[1] or » ICD-10-CM code for spinal cord compression (G95.9)[1] or » History of radiation to the bone, bone surgery, and/or hospitalization for SRE » ICD-10-CM code for chronic kidney disease (N18.1 – N18.9, I12.0 – I13.2)[1]	• Establishing evidence of SRE and reduced renal function, as well as confirming lack of therapy, may require patient chart review • These patients may include those who were previously treated with bone-targeting therapy and those who are treatment-naïve

HCPCS = Healthcare Common Procedure Coding System; ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification.

Amgen is committed to protecting patient privacy and the Amgen field force is not permitted to access any protected health information. Therefore, any report with patient-specific data must not be handled by, shared with, or discussed by a healthcare professional with any agent of Amgen for any reason.

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 additional Important Safety Information on pages 6-7.

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YOUR PATIENTS COULD PAY AS LITTLE AS $5* OUT OF POCKET, REGARDLESS OF INCOME

The Amgen FIRST STEP™ Program can help your eligible commercially insured patients meet their deductible, co-insurance, and co-payment.

- $0 out of pocket for first dose or cycle
- $5 out of pocket for subsequent doses or cycles, up to the brand program benefit maximum
- No income eligibility requirement

For additional program details, please visit AmgenFIRSTSTEP.com or call 1-888-65-STEP1 (1-888-657-8371) from 9 am to 8 pm ET, Monday through Friday.

For additional information regarding Amgen Assist 360™ access resources, see back cover.

Patient Eligibility Requirements*

- Must be prescribed XGEVA®
- Must have private commercial health insurance that covers medication costs for XGEVA®
- Must not be a participant in any federal-, state-, or government-funded healthcare program such as Medicare, Medicare Advantage, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), the Department of Defense (DoD), or TRICARE®
- May not seek reimbursement for value received from the Amgen FIRST STEP™ Program from any third-party payers, including flexible spending accounts or healthcare savings accounts. If at any time patients begin receiving coverage under any federal-, state-, or government-funded healthcare program, patients will no longer be eligible to participate in the Amgen FIRST STEP™ Program and must call 1-888-65-STEP1 (1-888-657-8371) Monday through Friday, 9 am–8 pm ET to stop participation. Restrictions may apply. Amgen reserves the right to revise or terminate this program, in whole or in part, without notice at any time. This is not health insurance. Program invalid where otherwise prohibited by law

Coverage Limits

- Program covers out-of-pocket medication costs for the Amgen product only. Program does not cover any other costs related to office visit or administration of the Amgen product
- No out-of-pocket cost for first dose; $5 out-of-pocket cost for subsequent dose or cycle; maximum benefit of $10,000 per patient per calendar year. Patient is responsible for costs above these amounts
- Ongoing activation of the Amgen FIRST STEP™ card is contingent on the submission of the required Explanation of Benefits (EOB) form by the healthcare provider's office within 45 days of use of the Amgen FIRST STEP™ card. Patients will be responsible for reimbursing the program for all amounts paid out if the EOB for the date of service is not received within 45 days

*Other restrictions apply. Not valid where prohibited by law. Amgen reserves the right to revise or terminate this program, in whole or in part, without notice at any time.

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INFORMATION FOR PATIENTS WITH MULTIPLE MYELOMA (MM)

PATIENT TYPES	SEARCH CRITERIA TO CONSIDER	HELPFUL SEARCH TIPS
Patients with MM receiving antimyeloma therapy who are currently treated with bone-targeting therapy	• ICD-10-CM code for MM (C90.00 – C90.01)[1] AND • Prescribed antimyeloma therapy AND • One of the following HCPCS codes for bone-targeting therapy within the past 4 weeks: » J3489[2] for zoledronic acid or » J2430[2] for pamidronate	• Confirming use of antimyeloma therapy may require a patient chart review
Patients with MM receiving antimyeloma therapy who are currently treated with bone-targeting therapy and have reduced renal function	• ICD-10-CM code for MM (C90.00 – C90.01)[1] AND • Prescribed antimyeloma therapy AND • ICD-10-CM code for chronic kidney disease (N18.1 – N18.9, I12.0 – I13.2)[1] AND • One of the following HCPCS codes for bone-targeting therapy within the past 4 weeks: » J3489[2] for zoledronic acid or » J2430[2] for pamidronate	• Establishing evidence of reduced renal function and confirming use of antimyeloma therapy may require patient chart review
Patients with MM receiving antimyeloma therapy who are not currently treated with bone-targeting therapy	• ICD-10-CM code for MM (C90.00 – C90.01)[1] AND • Prescribed antimyeloma therapy AND • None of the following HCPCS codes for bone-targeting therapy within the past 4 weeks: » J3489[2] for zoledronic acid and » J2430[2] for pamidronate and » J0897[2] for denosumab	• Confirming use of antimyeloma therapy and lack of bone-targeting therapy may require patient chart review • These patients may include those who were previously treated with bone-targeting therapy and those who are treatment-naïve
Patients with MM receiving antimyeloma therapy who are not currently treated with bone-targeting therapy and have reduced renal function	• ICD-10-CM code for MM (C90.00 – C90.01)[1] AND • Prescribed antimyeloma therapy AND • ICD-10-CM code for chronic kidney disease (N18.1 – N18.9, I12.0 – I13.2)[1] AND • None of the following HCPCS codes for bone-targeting therapy within the past 4 weeks: » J3489[2] for zoledronic acid and » J2430[2] for pamidronate and » J0897[2] for denosumab	• Establishing evidence of reduced renal function, as well as confirming use of antimyeloma therapy and lack of bone-targeting therapy, may require patient chart review • These patients may include those who were previously treated with bone-targeting therapy and those who are treatment-naïve

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 additional Important Safety Information on pages 6-7.

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AMGEN ASSIST 360™

Support, Simplified

RESOURCES FOR YOUR PATIENTS

NURSE AMBASSADORS*

Patients are connected with a single point of contact who can help them find resources that are most important to them. Amgen Nurse Ambassadors are there to support, not replace, your treatment plan and are trained to assist a patient with financial coverage and referrals to resources that may help their emotional wellness throughout their treatment journey.†

REFERRALS TO DAY-TO-DAY LIVING RESOURCES†

Patients can learn about independent nonprofit organizations that may provide community resources, one-on-one counseling services, and local support groups.

FINANCIAL SUPPORT OPTIONS FOR ANY INSURANCE TYPE

Whatever type of insurance your patients have—even if they have none—we can help them understand how their Amgen medicine may be covered and refer them to programs that may be able to help them afford it.†

- For eligible‡ commercially insured patients, the Amgen FIRST STEP™ co-pay program can help
- For patients with government insurance like Medicare, we provide referrals to independent nonprofit patient assistance programs that may be able to help them afford the co-pay cost of their medicine†
- For uninsured patients, the Amgen Safety Net Foundation, a nonprofit patient assistance program sponsored by Amgen, helps qualified patients access Amgen medicines at no cost

Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4-ASSIST (1-888-427-7478) or AmgenAssist360.com.

*Amgen Nurse Ambassadors are there to support, not replace, your treatment plan and do not provide medical advice or case management services. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

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

‡Terms, conditions, and program maximums apply. This program is not open to patients receiving prescription reimbursement under any federal-, state-, or government-funded healthcare program. Not valid where prohibited by law.

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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.

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Important Safety Information (continued)

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.

Please click here for Prescribing Information.

AMGEN ASSIST 360™

Support, Simplified

SUPPORT FROM EVERY ANGLE

RELY ON AMGEN ASSIST 360™, A SINGLE POINT OF CONTACT, TO PROVIDE SUPPORT DESIGNED AROUND YOU AND YOUR PATIENTS.

FOR YOUR OFFICE

BENEFIT VERIFICATION

Submit, store, and retrieve benefit verifications electronically for all patients currently on Amgen medications with ease from our secure Amgen Assist 360™ Provider Portal.*

REIMBURSEMENT COUNSELORS

Call an Amgen Reimbursement Counselor directly for your benefit verification needs.

FIELD REIMBURSEMENT SPECIALISTS

Schedule a remote or live appointment with a Field Reimbursement Specialist who can assist with:

- General reimbursement questions, including product coding and billing information
- Prior authorization and claims denials/appeals
- Payer-specific inquiries and policy updates
- Financial assistance, including Amgen FIRST STEP™ co-pay program support

AMGEN THERAPY LOCATOR

AmgenTherapyLocator.com is a searchable database to locate alternative injection sites where XGEVA® can be administered to your patients.†

FOR YOUR PATIENTS

NURSE AMBASSADORS‡

Patients are connected with a single point of contact who can help them find resources that are most important to them.

REFERRALS TO DAY-TO-DAY LIVING RESOURCES§

Patients can learn about independent nonprofit organizations that may provide community resources, one-on-one counseling services, and local support groups.

FINANCIAL AND CO-PAY ASSISTANCE

For eligible** commercially insured patients, the Amgen FIRST STEP™ co-pay program can help.

*Amgen Assist 360™ can refer patients to independent nonprofit patient assistance programs that may be able to help them afford the co-pay costs for their prescribed medicine.

†The information on this website is reported by independent third-party treatment sites. It is not comprehensive of all sites that handle the therapies listed, and Amgen does not confirm accuracy or otherwise endorse any treatment sites.

‡Amgen Nurse Ambassadors are there to support, not replace, your treatment plan and do not provide medical advice or case management services. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

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

**Terms, conditions, and program maximums apply. This program is not open to patients receiving prescription reimbursement under any federal-, state-, or government-funded healthcare program. Not valid where prohibited by law.

Contact Amgen Assist 360™ for reimbursement and access resources at 1-888-4-ASSIST (1-888-427-7478) or AmgenAssist360.com.

References

1. Centers for Medicare & Medicaid Services. 2021 ICD-10-CM Code Descriptions in Tabular Order. Available at ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2021/. Accessed September 2, 2020.
2. Centers for Medicare & Medicaid Services. 2020 Table of Drugs. Available at https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2020-Table-of-Drugs.pdf. Accessed September 2, 2020.

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