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 <u>click here</u> for the 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.

ITEM	CODING INFORMATION (HCPCS¹/CPT®²/ICD-10-CM³)	NOTES
XGEVA®	J0897, SC injection, denosumab, 1 mg	XGEVA® is supplied as a 120 mg dose; its NDC is 55513-0730-014
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.

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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.

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^{*} Some payers, including Médicare, 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.

Sample CMS 1500 Form — Physician Office Administration

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9. ADDITIONAL CLAIM INFORMATION (Designate		o. NPI S	econdary malignant	neoplasm of bone.	i
9. ADDITIONAL CLAIM INFORMATION (Designation)	ed by NOCC)	D	IAGNOSIS CODE (B	OX 24E)	
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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 (HCPCS1/CPT®2/ICD-10-CM3)	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 55513-0730-014
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.

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Sample CMS 1500 Form — Physician Office Administration

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SIGNED Manual avail				ation of X		TPE				1197 FORM	1500 (02-12)



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 55513-0730-014
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.

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^{*}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.

Sample CMS 1500 Form — Physician Office Administration

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HEALTH INSURANCE CLAIM FORM	CARRIER
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(Medicare#) (Medicaid#) (ID#/DoD#) (Member ID#) (ID#)	D#) 4. INSURED'S NAME (Last Name, First Name, Middle Initial)
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TY STATE 8. RESERVED FOR NUCC USE	CITY STATE
Anytown P CODE TELEPHONE (Include Area Code)	ZIP CODE TELEPHONE (Include Area Code)
01010 (xxx) xxx-xxxx	ZIP CODE TELEPHONE (Include Area Code) () 11. INSURED'S POLICY GROUP OR FECA NUMBER
OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) 10. IS PATIENT'S CONDITION RELATED TO:	11. INSURED'S POLICY GROUP OR FECA NUMBER
OTHER INSURED'S POLICY OR GROUP NUMBER a. EMPLOYMENT? (Current or Previous)	a. INSURED'S DATE OF BIRTH SEX
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INSURANCE PLAN NAME OR PROGRAM NAME	c. INSURANCE PLAN NAME OR PROGRAM NAME NOSIS CODE (BOX 21)
PRODUCT CODE (BOX 24D) diagr	ment appropriate ICD-10-CM nosis code(s) corresponding to patient's
per to myself or to the party who accepts a	nosis. Line A - primary diagnosis code.
An ex	kample of a primary diagnosis code des: E83.52, hypercalcemia.
SIGNED DATE	natients receiving treatment for CUPATION
XX XX QUAL QUAL QUAL hyper	rcalcemia of malignancy, payers may
Traine of the entire to the trainer of the trainer	require to document the diagnosis code ribing the malignancy; however, specific
D. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)	ng requirements may vary by payer.
DIAGNOSIS OR NATURE OF ILL NESS OR INJURY Relate A-L to service line below (24F)	NOSIS CODE (BOX 24E)
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J. K. L.	F. G. H. I. J.
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Healthcare providers should consult the payer or Medicare contractor to determine which code is	



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 (HCPCS1/CPT®2/ICD-10-CM3)	NOTES
XGEVA®	J0897, subcutaneous (SC) injection, denosumab, 1 mg	XGEVA® is supplied as a 120 mg dose administered every 4 weeks; its NDC is 55513-0730-014
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Office visit	Relevant Evaluation and Management (E&M) code*†	See payer guidelines
Diagnosis/ Condition	Appropriate ICD-10-CM code(s) for patient condition	Examples: C90.00 Multiple myeloma not having achieved remission C90.01 Multiple myeloma in remission C90.02 Multiple myeloma in relapse Allowable diagnosis codes may vary by payer

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Sample CMS 1500 Form — Physician Office Administration

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EALTH INSURANCE CLAIM FORM			CARRIER
PROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12			Ĭ
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PATIENT'S NAME (Last Name, First Name, Middle Initial)	3. PATIENT'S BIRTH DATE SEX	4. INSURED'S NAME (Last Name, First Name, Middle Initial)	
Doe, John D	XX XX XX M	Doe, John D	
PATIENT'S ADDRESS (No., Street) 5555 Any Street	6. PATIENT RELATIONSHIP TO INSURED	7. INSURED'S ADDRESS (No., Street)	
TY STATE	Self Spouse Child Other 8. RESERVED FOR NUCC USE	CITY STATE	
Anytown	S. HESERVED I STRAGES USE	STATE	
P CODE TELEPHONE (Include Area Code)	1	ZIP CODE TELEPHONE (Include Area Code)	MA
01010 (xxx) xxx-xxxx			
OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	10. IS PATIENT'S CONDITION RELATED TO:	11. INSURED'S POLICY GROUP OR FECA NUMBER	Ĭ.
OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous)	a. INSURED'S DATE OF BIRTH SEX	
SE. MONDER	YES NO	MM DD YY M F	INSURED INFORMATION
RESERVED FOR NUCC USE	b. AUTO ACCIDENT? PLACE (State)		
	YES NO		AND
RESERVED FOR NUCC USE	c. OTHER ACCIDENT?	c. INSURANCE PLAN NAME OR PROGRAM NAME	Ä
	YES NO		PATIENT
INSURANCE PLAN NAME OR PROGRAM NAME	10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes. complete items 9, 9a, and 9d,	4
PRODUCT CODE (BOX 24D)	G & SIGNING THIS FORM.	YES NO <i>If yes</i> , complete items 9, 9a, and 9d.	9
Document use of product with J0897,		DSIS CODE (BOX 21) an or supplie	
SC injection, denosumab, 1 mg.	Docume	ent appropriate ICD-10-CM	
S GNED	notiont'	sis code(s) corresponding to	<u> </u>
MM DD YY		s diagnosis. Line A — primary sis code.	Ņ
XX XX XX QUAL. 17 ' NAME OF REFERRING PROVIDER OR OTHER SOURCE 17			
17	b. NPI C90.00,	e diagnosis code includes: multiple myeloma not having	r
D. A DOITIONAL CLAIM INFORMATION (Designated by NUCC)		d remission.	-
	DIAGNO	OSIS CODE (BOX 24E)	
. D AGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to ser	vice line below (24E)	diagnosis from Box 21, relating to	
C90.0X B C. I		PT/HCPCS code listed in Box 24D.	
F. L G. l	Н. Ц	I, i i i i i i i i i i i i i i i i i i i	
J. L K. K. K. H. A. DATE(S) OF SERVICE B. C. D. PROC	EDURES, SERVICES, OR SUPPLIES E.	F. G. H. I. J.	
	ain Unusual Circumstances) DIAC NOSIS PCS MODIFIER POINTER		
		SERVICE UNITS (BOX 24G
xx xx xx xx xx 11 J08	97 A	xxx xx 120 Report unit of ser	vice. For
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x xx xx xx xx xx 11 96X	XX A	dose is 120 mg, pe	er label).
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PROCEDURE CODE (BO	0X 24D1	NPI	\ <u>e</u>
Document product adm			PHYSICIAN
appropriate CPT code.		NPI	<u></u>
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96372, therapeutic properties		NPI	
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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.

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, pain in extremity, nasopharyngitis, musculoskeletal pain, toothache, vomiting, hypophosphatemia, constipation, diarrhea, and cough. The most frequent serious adverse reactions were osteonecrosis of the jaw, bone giant cell tumor, anemia, pneumonia, and back pain. The most frequent adverse reaction resulting in discontinuation of XGEVA® was osteonecrosis of the jaw.
- 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.

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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.





^{*} 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.