

HOSPITAL 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 [click here](#) for the
XGEVA® full Prescribing Information.

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

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	REVENUE CODE ¹	CODING INFORMATION (HCPCS ² /CPT ^{®3} /ICD-10-CM ⁴)	NOTES
XGEVA®	<p>Medicare: 0636, drugs requiring detailed coding</p> <p>Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer</p>	J0897, SC injection, denosumab, 1 mg	XGEVA® is supplied as a 120 mg dose; its NDC is 55513-0730-01 ⁵
Administration	Appropriate revenue code for the cost center in which the service is performed	96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular; OR 96401, chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic	<p>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.^{3,6} However, third-party payers (or local carriers in the case of Medicare) make the determination for which specific codes are appropriate for billing</p> <p>Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of XGEVA®</p>
Diagnosis/Condition	N/A	Appropriate ICD-10-CM code(s) for patient condition	<p>Example:</p> <p>C79.51 Secondary malignant neoplasm of bone</p> <p>Allowable diagnosis codes may vary by payer</p>

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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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The CMS 1450 for Hospital Outpatient

Sample UB-04 (CMS 1450) Form — Hospital Outpatient Administration

1 Anytown Hospital 100 Main Street Anytown, Anystate 01010		2	3a PAT. CNTL. #	4 TYPE OF BILL
8 PATIENT NAME a Smith, Jane		9 PATIENT ADDRESS a 123 Main Street, Anytown, Anystate 12345		
10 BIRTHDATE	11 SEX	12 DATE	13 HR	14 TYPE
15 SRC	16 DHR	17 STAT	18	19
20	21	22	23	24
25	26	27	28	29 ACDT STATE
30	31 OCCURRENCE CODE		32 OCCURRENCE DATE	
33	34 OCCURRENCE CODE		35 OCCURRENCE DATE	
36	37		38	
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE
45 SERV. DATE		46 SERV. UNITS		47 TOTAL CHARGES
48 NON-COVERED CHARGES		49		
0636 Drugs/detailed coding		J0897		MDDYY 120
0510 Clinic		96372 OR 96401		MDDYY 1
XXXXX		XXXXX		
XXXXX		XXXXX		
PAGE OF		CREATION DATE		TOTALS
50 PAYER NAME		51 HEALTH PLAN ID		52 REL INFO
53 ASG BEN.		54 PRIOR PAYMENTS		55 EST. AMOUNT DUE
56 NPI		57 OTHER PRV ID		
58 ICD-10-CM		59 P REL		60 INSURED'S UNIQUE ID
61 GROUP NAME		62 INSURANCE GROUP NO.		
63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME
66 ICD-10-CM		68		
69 ADMIT DX		70 PATIENT REASON DX		71 PPS CODE
72 ECI		73		
74 PRINCIPAL PROCEDURE CODE		75 OTHER PROCEDURE CODE		76 ATTENDING NPI
77 OPERATING NPI		78 OTHER NPI		
79 OTHER NPI		80 REMARKS		
81CC a		81CC b		
81CC c		81CC d		

SERVICE UNITS (BOX 46)
Report units of service. XGEVA® dose is 120 mg, per label.

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)
Product
Medicare: Use revenue code 0636, drugs requiring detailed coding.
Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).
Related administration procedure
Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic).

PRODUCT AND PROCEDURE CODES (BOX 44)
Product
Use J0897, SC injection, denosumab, 1 mg.
Related administration procedure
Use CPT code representing procedure performed, such as 96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular; or 96401, chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic.
Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of XGEVA®.

DIAGNOSIS CODES (BOX 67)
Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis, eg, C79.51, secondary malignant neoplasm of bone.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes 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®
(denosumab) injection
120 mg/1.7 mL vial

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	REVENUE CODE ¹	CODING INFORMATION (HCPCS ² /CPT ³ /ICD-10-CM ⁴)	NOTES
XGEVA®	Medicare: 0636, drugs requiring detailed coding	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 ⁵
	Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer		
Administration	Appropriate revenue code for the cost center in which the service is performed	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. ^{3,6} 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®
Diagnosis/Condition	N/A	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

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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.

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Sample UB-04 (CMS 1450) Form — Hospital Outpatient Administration

1 Anytown Hospital 100 Main Street Anytown, Anystate 01010		2	3a PAT. CNTL. # b. MED. REC. #	4 TYPE OF BILL																																								
8 PATIENT NAME a Smith, Jane		9 PATIENT ADDRESS a 123 Main Street, Anytown, Anystate 12345																																										
10 BIRTHDATE	11 SEX	12 DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	18	19	20	21	22-28 CONDITION CODES			29 ACCT STATE	30																												
31 OCCURRENCE CODE	32 OCCURRENCE DATE	33 OCCURRENCE CODE	34 OCCURRENCE DATE	35 OCCURRENCE CODE	36 OCCURRENCE SPAN FROM THRU		37	38																																				
39 CODE							39 VALUE CODES AMOUNT					39 VALUE CODES AMOUNT																																
42 REV. CD. 0636 0510							43 DESCRIPTION Drugs/detailed coding Clinic					44 HCPCS / RATE / HIPPS CODE J0897 96372 OR 96401					45 SERV. DATE MDDYY MDDYY					46 SERV. UNITS 120 1					47 TOTAL CHARGES XXXXX XXXXX					48 NON-COVERED CHARGES					49							
PAGE <u> </u> OF <u> </u>																							CREATION DATE										TOTALS											
50 PAYER NAME										51 HEALTH PLAN ID										52 REL. INFO					53 ASS. BEN.					54 PRIOR PAYMENTS					55 EST. AMOUNT DUE					56 NPI				
57 OTHER PRV ID										58 ICD-10-CM										59 P. PREL.					60 INSURED'S UNIQUE ID					61 GROUP NAME					62 INSURANCE GROUP NO.									
63 TREATMENT AUTHORIZATION CODES										64 DOCUMENT CONTROL NUMBER										65 EMPLOYER NAME																								
66 D48.0																																												
69 ADMIT DX					70 PATIENT REASON DX					71 FPS CODE					72 ECI					73																								
74 PRINCIPAL PROCEDURE CODE					a. OTHER PROCEDURE CODE					b. OTHER PROCEDURE CODE					75					76 ATTENDING NPI					QUAL																			
77 OPERATING NPI					QUAL					78 OTHER NPI					QUAL					79 OTHER NPI					QUAL																			
80 REMARKS					81CC a					b					c					d					LAST					FIRST														

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)
Product
 Medicare: Use revenue code 0636, drugs requiring detailed coding.
 Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).
Related administration procedure
 Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic).

PRODUCT AND PROCEDURE CODES (BOX 44)
Product
 Use J0897, SC injection, denosumab, 1 mg.
Related administration procedure
 Use CPT code representing procedure performed, such as 96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular; or 96401, chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic.
 Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of XGEVA®.

SERVICE UNITS (BOX 46)
 Report units of service. XGEVA® dose is 120 mg, per label.

DIAGNOSIS CODES (BOX 67)
 Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis, eg, D48.0, neoplasm of uncertain behavior of bone and articular cartilage.

Giant Cell Tumor of Bone

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes 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®
 (denosumab) injection
 120 mg/1.7 mL vial

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

ITEM	REVENUE CODE ¹	CODING INFORMATION (HCPCS ² /CPT ³ /ICD-10-CM ⁴)	NOTES
XGEVA®	Medicare: 0636, drugs requiring detailed coding	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 ⁵
	Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer		
Administration	Appropriate revenue code for the cost center in which the service is performed	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. ^{3,6} 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®
Diagnosis/Condition	N/A	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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Important Safety Information

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Sample UB-04 (CMS 1450) Form — Hospital Outpatient Administration

1 Anytown Hospital 100 Main Street Anytown, Anystate 01010	2		3a PAT. CNTL. #	4 TYPE OF BILL
b. MED. REC. #	5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM	7 THROUGH	
8 PATIENT NAME a Smith, Jane	9 PATIENT ADDRESS a 123 Main Street, Anytown, Anystate 12345	b	c	d
10 BIRTHDATE	11 SEX	12 DATE	13 HR	14 TYPE
15 SRC	16 DHR	17 STAT	18	19
20	21	22	23	24
25	26	27	28	29
30	31	32	33	34
35	36	37	38	39
40	41	42	43	44
45	46	47	48	49
50	51	52	53	54
55	56	57	58	59
60	61	62	63	64
65	66	67	68	69
70	71	72	73	74
75	76	77	78	79
80	81	82	83	84
85	86	87	88	89
90	91	92	93	94
95	96	97	98	99

SERVICE UNITS (BOX 46)
Report units of service.
XGEVA® dose is 120 mg,
per label.

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)
Product
Medicare: Use revenue code 0636, drugs requiring detailed coding.
Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).
Related administration procedure
Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic).

PRODUCT AND PROCEDURE CODES (BOX 44)
Product
Use J0897, SC injection, denosumab, 1 mg.
Related administration procedure
Use CPT code representing procedure performed, such as 96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular; or 96401, chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic.
Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of XGEVA®.

DIAGNOSIS CODES (BOX 67)
Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis, eg, 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.

Hypercalcemia of Malignancy

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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	REVENUE CODE ¹	CODING INFORMATION (HCPCS ² /CPT ³ /ICD-10-CM ⁴)	NOTES
XGEVA®	Medicare: 0636, drugs requiring detailed coding	J0897, SC injection, denosumab, 1 mg	XGEVA® is supplied as a 120 mg dose every 4 weeks; its NDC is 55513-0730-01 ⁵
	Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer		
Administration	Appropriate revenue code for the cost center in which the service is performed	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 a noncancer diagnosis or to substances, such as certain monoclonal antibody agents, and other biologic response modifiers. ^{3,6} 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®.
Diagnosis/Condition	N/A	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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15 SRC	16 DHR	17 STAT	18	19
20	21	22	23	24
25	26	27	28	29 ACCT STATE
30	31 OCCURRENCE CODE	32 OCCURRENCE DATE	33 OCCURRENCE CODE	34 OCCURRENCE DATE
35 OCCURRENCE CODE	36 OCCURRENCE DATE	37	38	39
42 REV. CD. 0636		43 DESCRIPTION Drugs/detailed coding		44 HCPCS / RATE / HIPPS CODE J0897
0510		Clinic		96372 OR 96401
				45 SERV. DATE MMDDYY
				46 SERV. UNITS 120
				47 TOTAL CHARGES XXXXX
				48 NON-COVERED CHARGES XXXXX
				49
PAGE OF		CREATION DATE		TOTALS
50 PAYER NAME		51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.
		54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI
				57 OTHER PRV ID
58 ICD-10-CM		60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
63 ICD-10-CM		64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME	
66 ICD-10-CM		67 ICD-10-CM		
68 ICD-10-CM		69 ICD-10-CM		
70 PATIENT REASON DX	71 FPS CODE	72 ECI	73	
74 PRINCIPAL PROCEDURE CODE	75 OTHER PROCEDURE CODE	76 ATTENDING NPI	77 OPERATING NPI	78 OTHER NPI
79 OTHER PROCEDURE CODE				
80 REMARKS	81CC a			
	b			
	c			
	d			

SERVICE UNITS (BOX 46)
Report units of service. XGEVA® dose is 120 mg, per label.

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)
Product
Medicare: Use revenue code 0636, drugs requiring detailed coding.
Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).
Related administration procedure
Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic).

PRODUCT AND PROCEDURE CODES (BOX 44)
Product
Use J0897, SC injection, denosumab, 1 mg.
Related administration procedure
Use CPT code representing procedure performed, such as 96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular; or 96401, chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic.
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DIAGNOSIS CODES (BOX 67)
Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis, eg, C90.00, multiple myeloma not having achieved remission.

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Multiple Myeloma

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.

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



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* 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.

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References

1. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17 – Drugs and Biologicals. 2017. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf>. Accessed October 16, 2017. 2. Centers for Medicare and Medicaid Services. 2017 Table of Drugs. <https://www.cms.gov/Medicare/Coding/HCPSCReleaseCodeSets/Downloads/2017-Table-of-Drugs.pdf>. Accessed October 19, 2017. 3. American Medical Association. Current Procedural Technology (CPT®) copyright 2017 American Medical Association. All rights reserved. 4. Centers for Medicare & Medicaid Services. 2018 ICD-10-CM Code Descriptions in Tabular Order. <https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2018-ICD-10-Code-Descriptions.zip>. Accessed October 16, 2017. 5. XGEVA® prescribing information, Amgen. 6. 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.



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