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®	**Medicare:** 0636, drugs requiring detailed coding **Other Payers:** 0250, general pharmacy; **OR** 0636, if required by a given payer	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	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:** C79.51 Secondary malignant neoplasm of bone 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.

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

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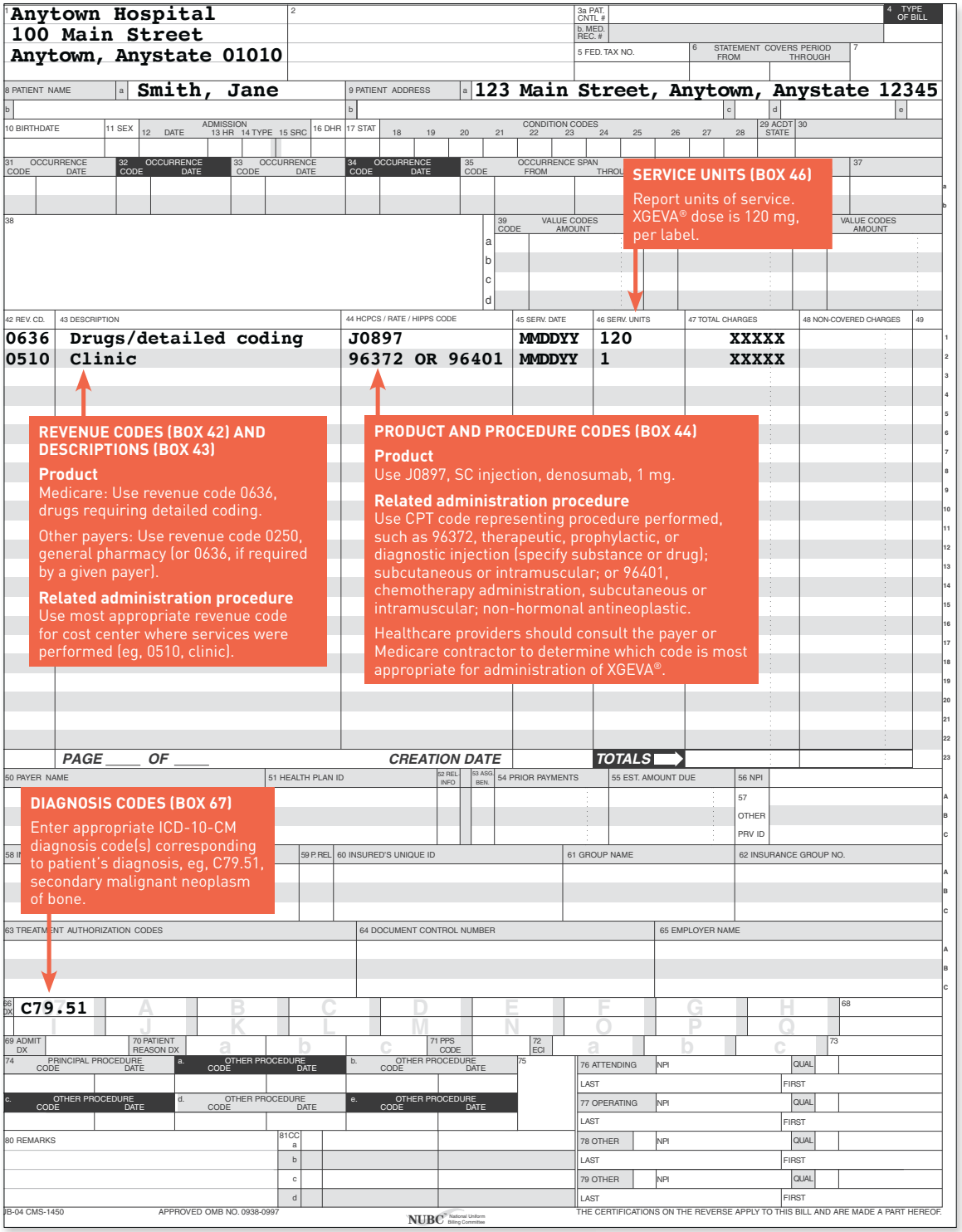
The CMS 1450 for Hospital Outpatient

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



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.

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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 **Other Payers:** 0250, general pharmacy; **OR** 0636, if required by a given payer	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]
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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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

8 PATIENT NAME: Smith, Jane

9 PATIENT ADDRESS: 123 Main Street, Anytown, Anystate 12345

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0636	Drugs/detailed coding	J0897	MMDDYY	120	XXXXX	
0510	Clinic	96372 OR 96401	MMDDYY	1	XXXXX	

PAGE ____ OF ____ CREATION DATE TOTALS

50 PAYER NAME | 51 HEALTH PLAN ID | 54 PRIOR PAYMENTS | 55 EST. AMOUNT DUE | 56 NPI

60 INSURED'S UNIQUE ID | 61 GROUP NAME | 62 INSURANCE GROUP NO.

63 TREATMENT AUTHORIZATION CODES | 64 DOCUMENT CONTROL NUMBER | 65 EMPLOYER NAME

67 D48.0

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, D48.0, neoplasm of uncertain behavior of bone and articular cartilage.

76 ATTENDING | 77 OPERATING | 78 OTHER | 79 OTHER — NPI, QUAL, LAST, FIRST

80 REMARKS | 81CC

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

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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 **Other Payers:** 0250, general pharmacy; **OR** 0636, if required by a given payer	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]
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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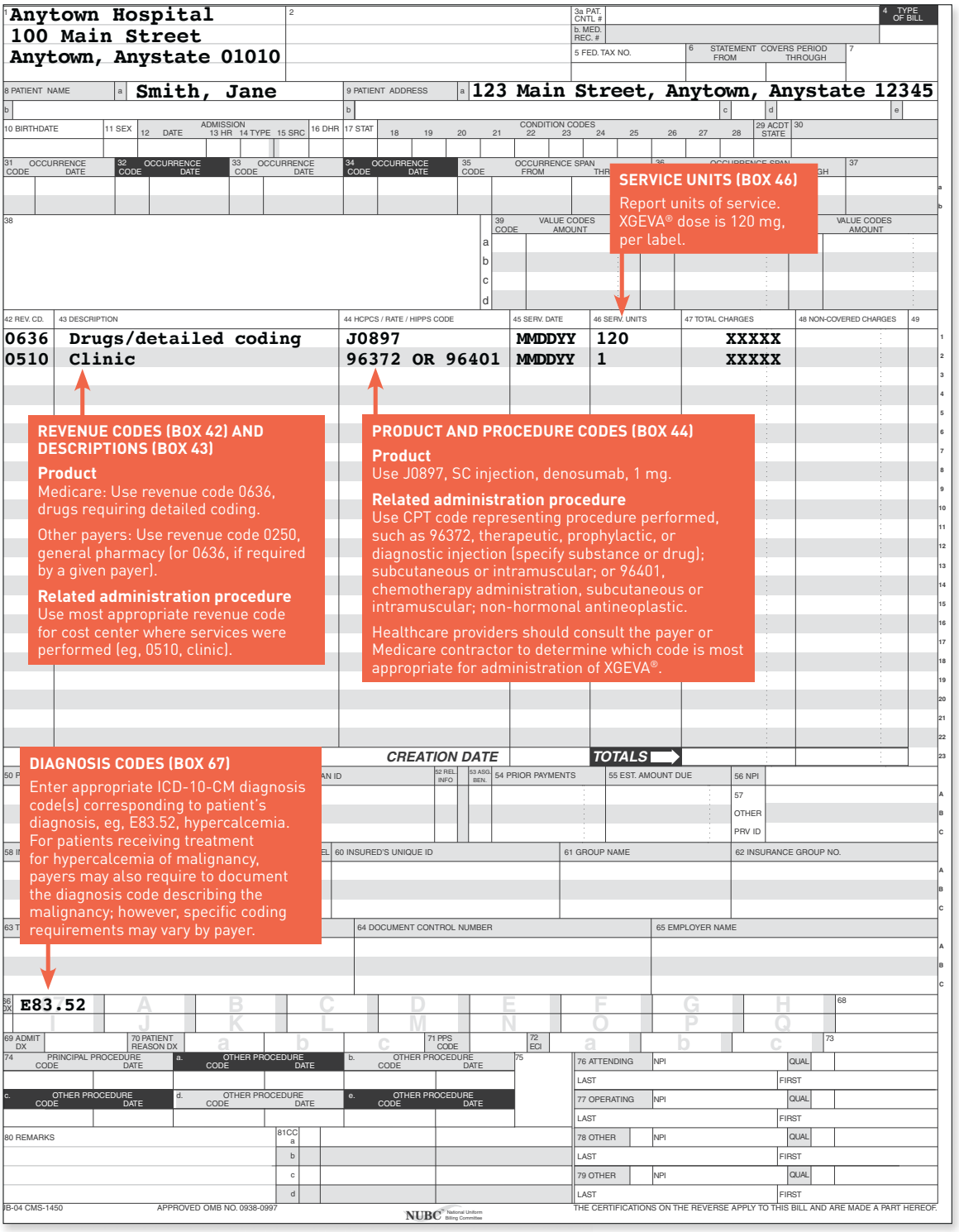

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XGEVA® (denosumab) injection
120 mg/1.7 mL vial

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®	**Medicare:** 0636, drugs requiring detailed coding **Other Payers:** 0250, general pharmacy; **OR** 0636, if required by a given payer	J0897, SC injection, denosumab, 1 mg	XGEVA® is supplied as a 120 mg dose every 4 weeks; 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	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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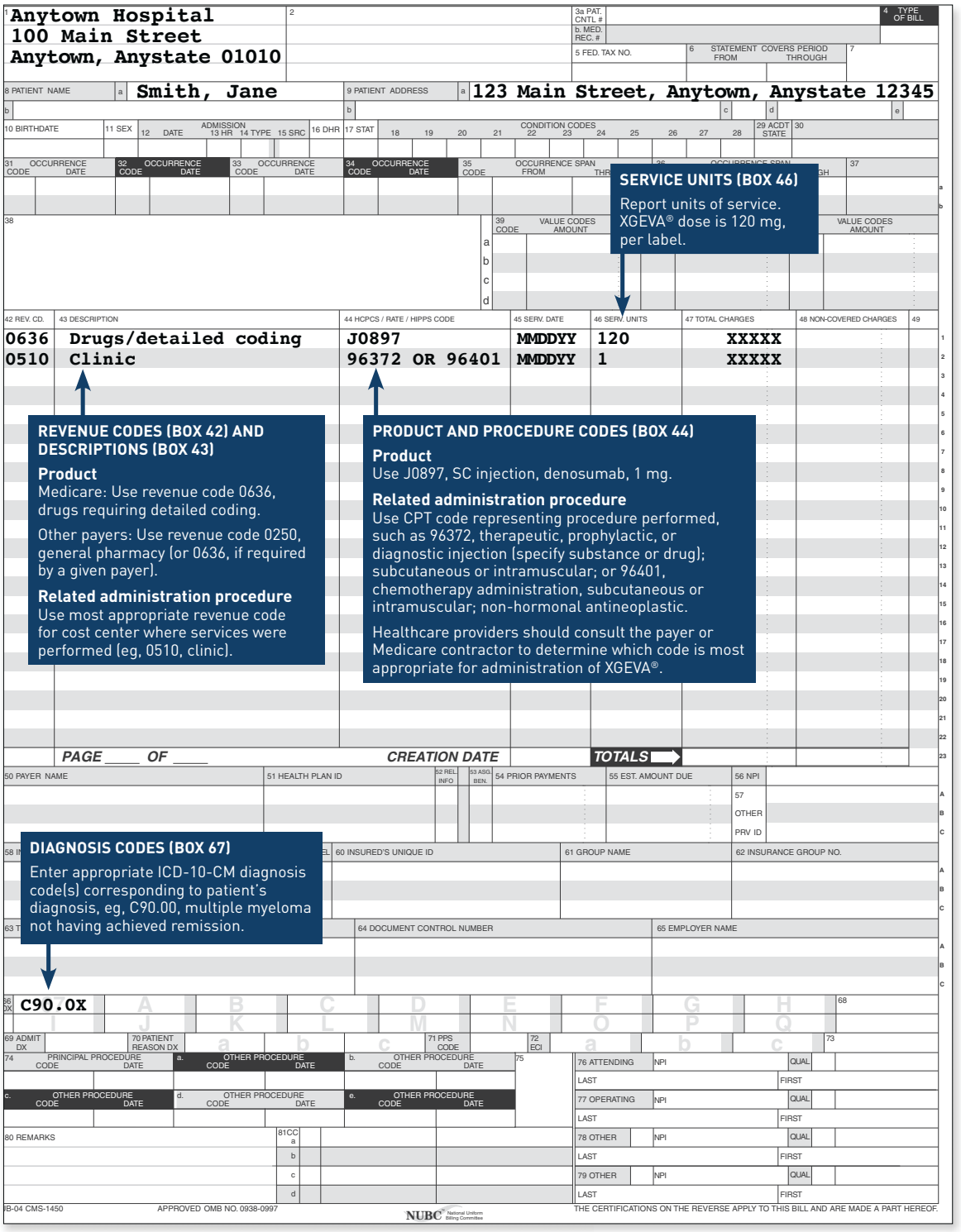

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XGEVA® (denosumab) injection
120 mg/1.7 mL vial

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.

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AMGEN ASSIST 360™

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 & 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/HCPCSReleaseCodeSets/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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Thousand Oaks, CA 91320-1799
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