PHYSICIAN OFFICE CODING AND BILLING INFORMATION SHEET FOR XGEVA®

Contact Amgen SupportPlus at (866) 264-2778, Monday - Friday 9:00 AM - 8:00 PM EST to learn how Amgen can help. Or visit AmgenSupportPlus.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	CODING INFORMATION (HCPCS[1]/CPT®[2]/ICD-10-CM[3])	NOTES
XGEVA®	J0897, SC injection, denosumab, 1 mg **JW/JZ Modifiers:** Effective for dates of service on or after July 1, 2023. Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.[4]	XGEVA® is supplied as a 120 mg dose; NDC numbers are: 55513-0730-01, 55513-730-21[5]
Administration	96372, therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular; **OR** 96401*, chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic	
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

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this section be considered a guarantee of coverage or reimbursement for any product or service.

CPT® is a registered trademark of the American Medical Association.

*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.[2,6] 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®.
†Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.
‡Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when Modifier 25 is billed.[5]

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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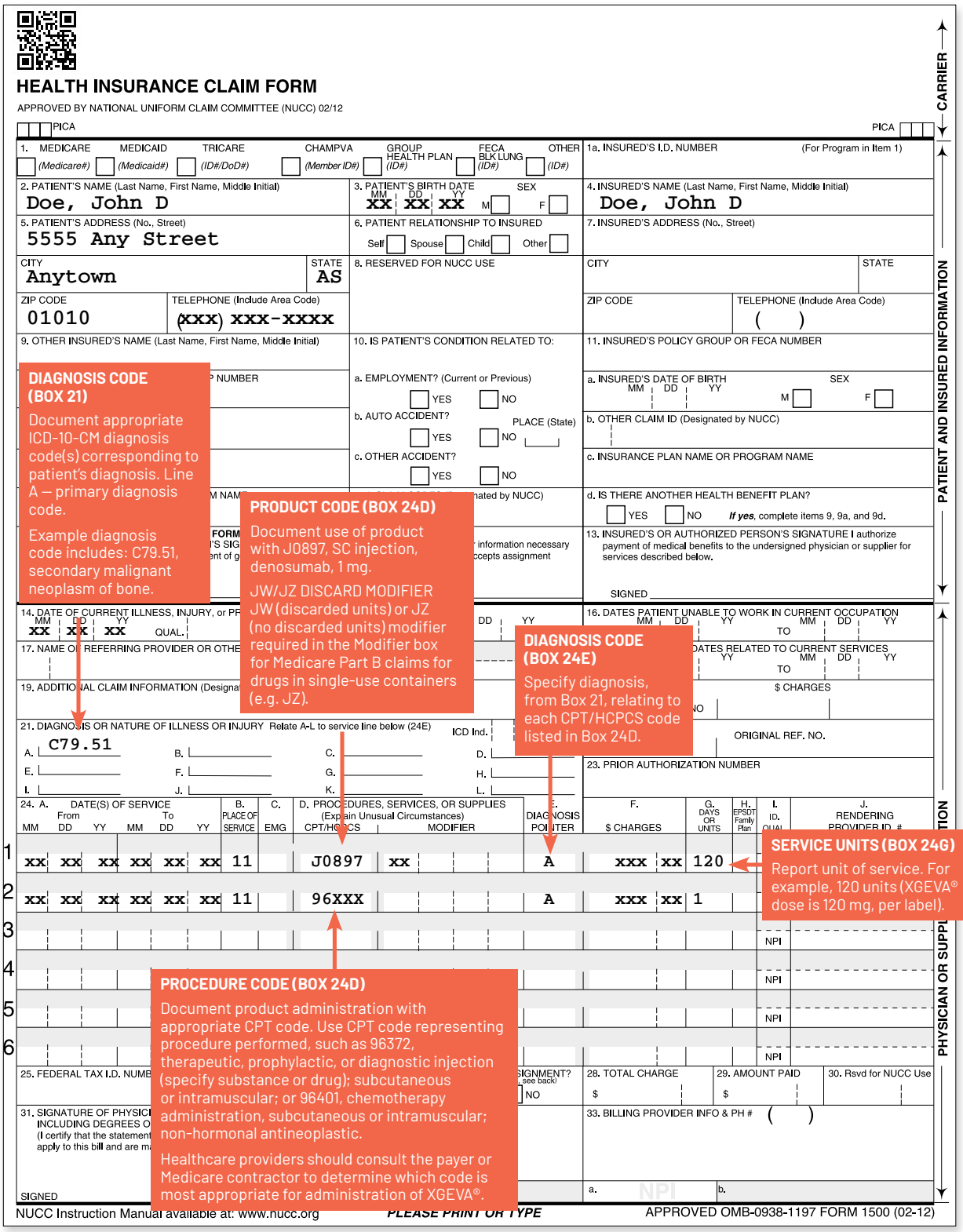
The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John D

3. PATIENT'S BIRTH DATE MM DD YY: xx xx xx SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John D

5. PATIENT'S ADDRESS (No., Street): 5555 Any Street

6. PATIENT RELATIONSHIP TO INSURED: Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE: 01010 TELEPHONE (Include Area Code): (xxx) xxx-xxxx

ZIP CODE TELEPHONE (Include Area Code)

9. 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

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PR MM DD YY: xx xx xx QUAL.

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHE

19. ADDITIONAL CLAIM INFORMATION (Designa

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. C79.51 B. C. D. E. F. G. H. I. J. K. L.

23. PRIOR AUTHORIZATION NUMBER

ORIGINAL REF. NO.

$ CHARGES

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 xx xx xx	xx xx xx	11		J0897	xx	A	xxx xx	120			NPI
2 xx xx xx	xx xx xx	11		96XXX		A	xxx xx	1			NPI
3											NPI
4											NPI
5											NPI
6											NPI

25. FEDERAL TAX I.D. NUME SIGNMENT? (see back) NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICI INCLUDING DEGREES O (I certify that the statement apply to this bill and are m

33. BILLING PROVIDER INFO & PH # ( )

SIGNED

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org *PLEASE PRINT OR TYPE* APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLI TION

DIAGNOSIS CODE (BOX 21)

Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A — primary diagnosis code.

Example diagnosis code includes: C79.51, secondary malignant neoplasm of bone.

PRODUCT CODE (BOX 24D)

Document use of product with J0897, SC injection, denosumab, 1 mg.

JW/JZ DISCARD MODIFIER

JW (discarded units) or JZ (no discarded units) modifier required in the Modifier box for Medicare Part B claims for drugs in single-use containers (e.g. JZ).

DIAGNOSIS CODE (BOX 24E)

Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

SERVICE UNITS (BOX 24G)

Report unit of service. For example, 120 units (XGEVA® dose is 120 mg, per label).

PROCEDURE CODE (BOX 24D)

Document product administration with appropriate CPT code. 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®.

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	CODING INFORMATION (HCPCS[1]/CPT®[2]/ICD-10-CM[3])	NOTES
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Office visit	Relevant Evaluation and Management (E&M) code†,‡	See payer guidelines
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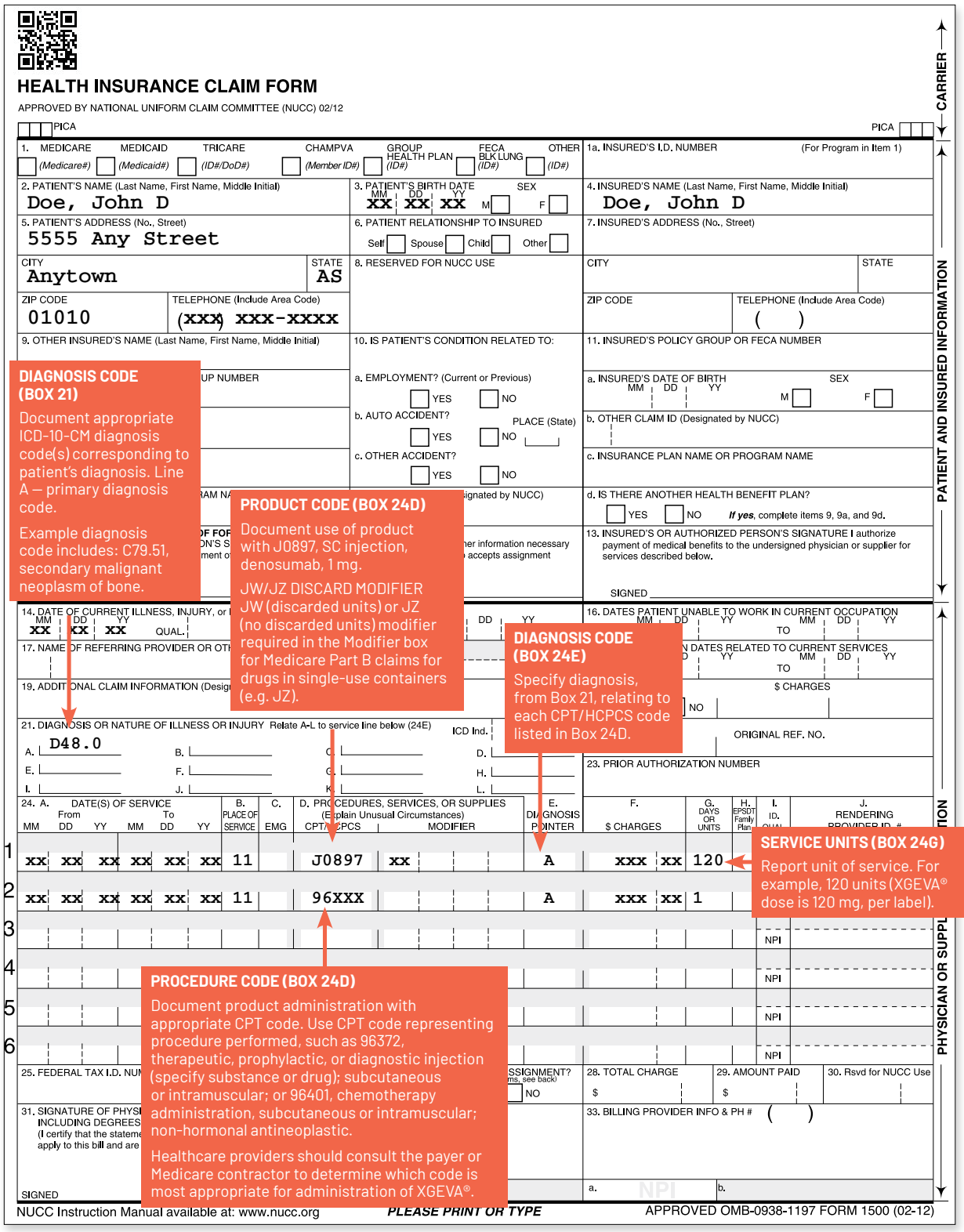
The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John D

3. PATIENT'S BIRTH DATE MM DD YY: xx xx xx SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John D

5. PATIENT'S ADDRESS (No., Street): 5555 Any Street

6. PATIENT RELATIONSHIP TO INSURED: Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE: 01010 TELEPHONE (Include Area Code): (xxx) xxx-xxxx

ZIP CODE TELEPHONE (Include Area Code): ( )

9. 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

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or MM DD YY: xx xx xx QUAL.

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTH

DATES RELATED TO CURRENT SERVICES MM DD YY TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Desig

$ CHARGES

NO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. D48.0 B. C. D.

E. F. G. H.

I. J. K. L.

ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID.	J. RENDERING PROVIDER ID. #
1 xx xx xx	xx xx xx	11		J0897	xx	A	xxx	xx 120			NPI
2 xx xx xx	xx xx xx	11		96XXX		A	xxx	xx 1			NPI
3											NPI
4											NPI
5											NPI
6											NPI

25. FEDERAL TAX I.D. NU SSIGNMENT? ms, see back) NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSI INCLUDING DEGREES (I certify that the statem apply to this bill and are

33. BILLING PROVIDER INFO & PH # ( )

SIGNED

a. NPI b.

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CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPL

DIAGNOSIS CODE (BOX 21)

Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A — primary diagnosis code.

Example diagnosis code includes: C79.51, secondary malignant neoplasm of bone.

PRODUCT CODE (BOX 24D)

Document use of product with J0897, SC injection, denosumab, 1 mg.

JW/JZ DISCARD MODIFIER

JW (discarded units) or JZ (no discarded units) modifier required in the Modifier box for Medicare Part B claims for drugs in single-use containers (e.g. JZ).

DIAGNOSIS CODE (BOX 24E)

Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

SERVICE UNITS (BOX 24G)

Report unit of service. For example, 120 units (XGEVA® dose is 120 mg, per label).

PROCEDURE CODE (BOX 24D)

Document product administration with appropriate CPT code. 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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XGEVA® (denosumab) injection 120 mg/1.7 mL vial

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
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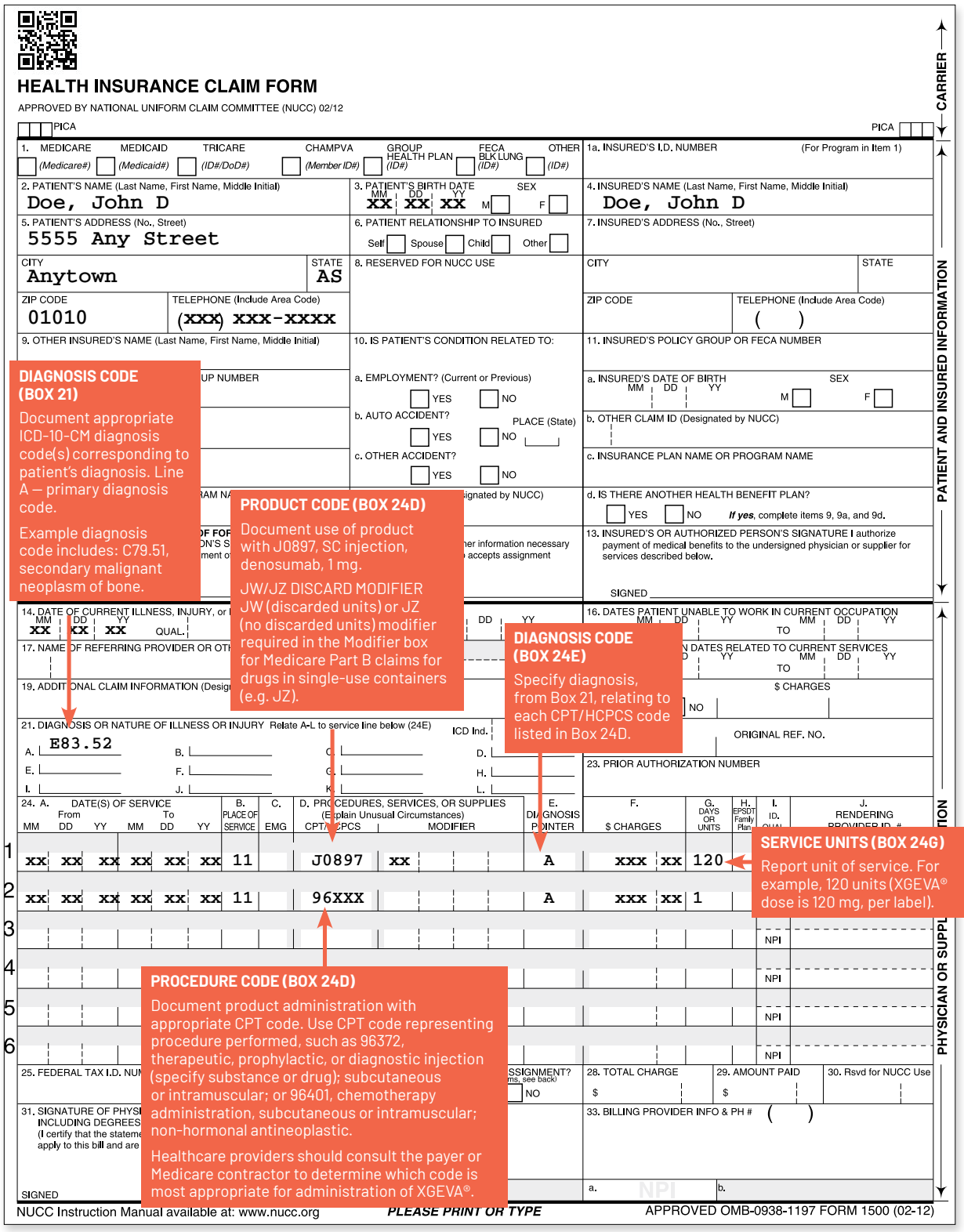

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CITY STATE

ZIP CODE: 01010 TELEPHONE (Include Area Code): (xxx) xxx-xxxx

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10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

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a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

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17. NAME OF REFERRING PROVIDER OR OTH

DATES RELATED TO CURRENT SERVICES MM DD YY TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Desig

$ CHARGES

NO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. E83.52 B. C. D.

E. F. G. H.

I. J. K. L.

ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

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4											NPI
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25. FEDERAL TAX I.D. NU SSIGNMENT? ms, see back) NO

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DIAGNOSIS CODE (BOX 24E)

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SERVICE UNITS (BOX 24G)

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PROCEDURE CODE (BOX 24D)

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The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this section be considered a guarantee of coverage or reimbursement for any product or service.

CPT® is a registered trademark of the American Medical Association.

*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.[2,6] 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®.
†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.[6]

Important Safety Information

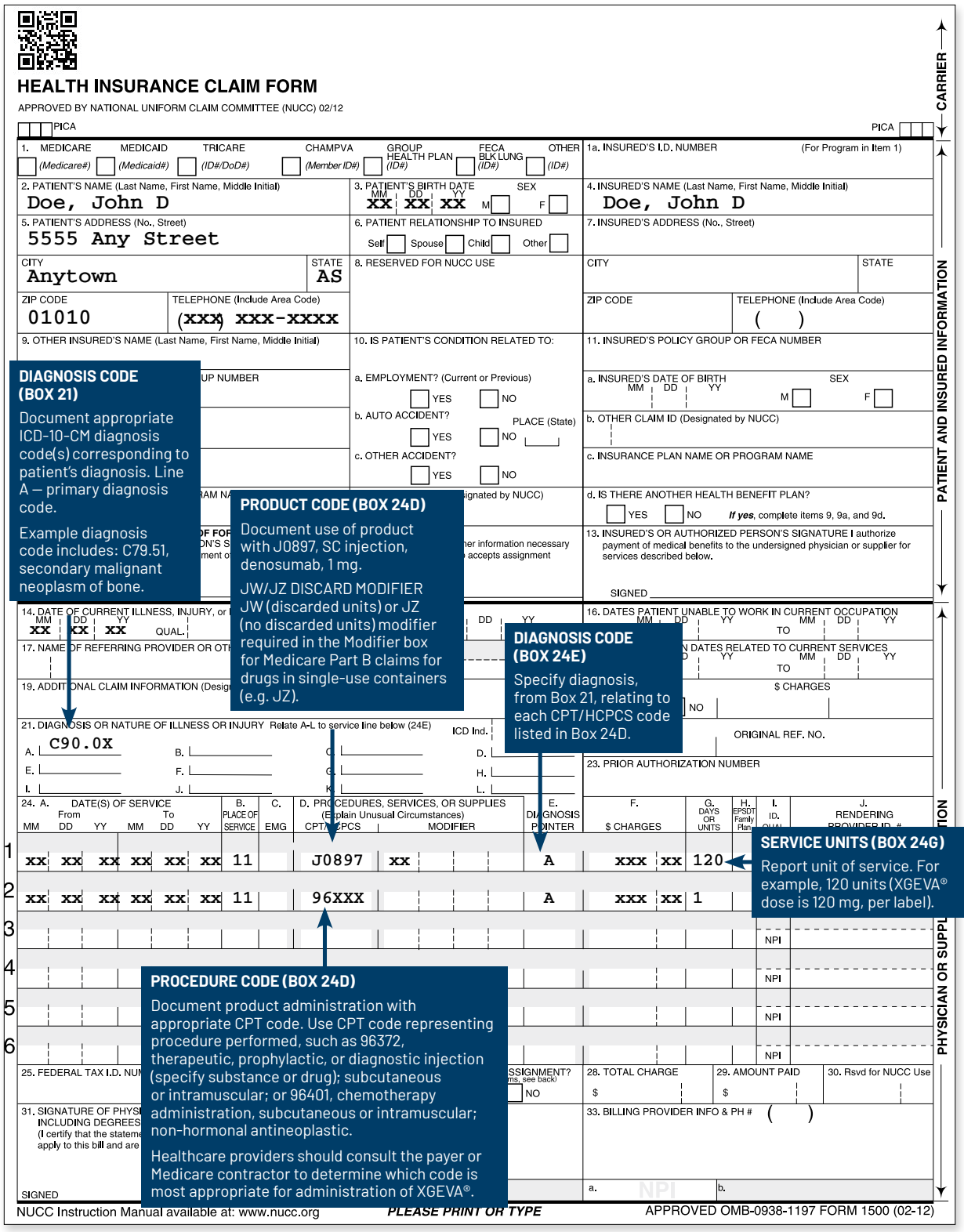
XGEVA® is contraindicated in patients with pre-existing hypocalcemia and clinically significant hypersensitivity to XGEVA®. XGEVA® can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Osteonecrosis of the jaw and atypical femoral fracture have been reported. Clinically significant hypercalcemia following treatment discontinuation in patients with Giant Cell Tumor of Bone and in patients with growing skeletons has been reported. Multiple vertebral fractures following discontinuation of treatment have been reported. XGEVA® can cause fetal harm.

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

Contact Amgen SupportPlus at (866) 264-2778 for reimbursement and accesses resources. Or visit AmgenSupportPlus.com.

The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John D

3. PATIENT'S BIRTH DATE MM DD YY: xx xx xx SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John D

5. PATIENT'S ADDRESS (No., Street): 5555 Any Street

6. PATIENT RELATIONSHIP TO INSURED: Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE: 01010 TELEPHONE (Include Area Code): (xxx) xxx-xxxx

ZIP CODE TELEPHONE (Include Area Code): ( )

9. 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

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or MM DD YY: xx xx xx QUAL.

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTH

19. ADDITIONAL CLAIM INFORMATION (Desig

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. C90.0X B. C. D.

E. F. G. H.

I. J. K. L.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. | J. RENDERING PROVIDER ID. #

1	xx	xx	xx	xx	xx	xx	11		J0897	xx	A	xxx	xx	120	NPI
2	xx	xx	xx	xx	xx	xx	11		96XXX		A	xxx	xx	1	NPI
3															NPI
4															NPI
5															NPI
6															NPI

25. FEDERAL TAX I.D. NU SSIGNMENT? ms, see back) NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYS INCLUDING DEGREES (I certify that the statem apply to this bill and are

33. BILLING PROVIDER INFO & PH # ( )

SIGNED

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org *PLEASE PRINT OR TYPE* APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPL

DIAGNOSIS CODE (BOX 21)

Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A — primary diagnosis code.

Example diagnosis code includes: C79.51, secondary malignant neoplasm of bone.

PRODUCT CODE (BOX 24D)

Document use of product with J0897, SC injection, denosumab, 1 mg.

JW/JZ DISCARD MODIFIER

JW (discarded units) or JZ (no discarded units) modifier required in the Modifier box for Medicare Part B claims for drugs in single-use containers (e.g. JZ).

DIAGNOSIS CODE (BOX 24E)

Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

SERVICE UNITS (BOX 24G)

Report unit of service. For example, 120 units (XGEVA® dose is 120 mg, per label).

PROCEDURE CODE (BOX 24D)

Document product administration with appropriate CPT code. 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®.

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

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 other denosumab products (e.g., Prolia®).

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.

Please click here for the Prescribing Information.

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

AMGEN® Support+

We're right here, right when you need us

Personalized support that you and your patients can count on across Amgen therapies.

Connect with us live: Call 866-264-2778

Monday through Friday - 9:00 AM TO 8:00 PM ET

Amgen SupportPlus Co-Pay Program

The Amgen SupportPlus Co-Pay Program may help eligible patients with commercial or private insurance lower their out-of-pocket costs.

- Pay as little as $0 out-of-pocket for each dose[§]
- Can be applied to deductible, co-insurance and co-payment[§]
- No income eligibility requirement

Visit AmgenSupportPlus.com now

[§]Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

Amgen® Field Reimbursement Specialists

A Reimbursement Specialist can provide live or virtual coverage and access resources to support your patients.

HCP Support Center

Our Amgen® SupportPlus Representatives can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.

Visit AmgenSupportPlus.com to learn more.

References: 1. Centers for Medicare and Medicaid Services. 2017 Table of Drugs. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2017-Table-of-Drugs.pdf. Accessed June 18, 2025. **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 June 18, 2025. **4.** CMS, Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy, available at https://www.cms.gov/medicare/medicare-fee-for-service payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf. Accessed June 18, 2025. **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 June 18, 2025.

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