

Considerations
for Complete
Claim Submission

CORRECT AND COMPLETE PATIENT
INFORMATION:

- ☐ Patient name
 - ID number
 - Health insurer name and/or group number
- ☐ Provider name
 - National provider ID number
 - Contact information

COLLECT PRODUCT AND BILLING INFORMATION:

- ☐ CPT/HCPCS code (J-Code) and units
- ☐ Determine appropriate JW or JZ modifier
- ☐ Diagnosis code to the highest level of specificity
 - Primary diagnosis code
- ☐ Identify appropriate administration code
- ☐ Determine prior authorization criteria (if required)
- ☐ Medicaid and commercial payers may require NDC reporting

SUPPLEMENTAL DOCUMENTATION
CONSIDERATIONS (INCLUDING TEST
RESULTS AND DATE AS APPROPRIATE):

- ☐ Original diagnostic T-score and/or FRAX predicted fracture risk
- ☐ Previous therapies
 - Reason for discontinuations
- ☐ Calcium and Vitamin D
- ☐ Prior osteoporosis-related fracture history
 - Location of fracture (provide ICD-10 number[s])
- ☐ Referring physician orders
- ☐ Risk factors for fracture
- ☐ Cardiovascular risk assessment
 - Confirm patients had no myocardial infarction or stroke events within the last 12 months

CONFIRM BILLING AND PAYER REQUIREMENTS:

- ☐ Omit or include punctuation as required in submitted claims
- ☐ Follow required time frame for submission after rendering service

Important Safety Information

POTENTIAL RISK OF MYOCARDIAL INFARCTION, STROKE, AND CARDIOVASCULAR DEATH

EVENTITY® may increase the risk of myocardial infarction, stroke and cardiovascular death. **EVENTITY®** should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. Monitor for signs and symptoms of myocardial infarction and stroke and instruct patients to seek prompt medical attention if symptoms occur. If a patient experiences a myocardial infarction or stroke during therapy, **EVENTITY®** should be discontinued.

In a randomized controlled trial in postmenopausal women, there was a higher rate of major adverse cardiac events (MACE), a composite endpoint of cardiovascular death, nonfatal myocardial infarction and nonfatal stroke, in patients treated with **EVENTITY®** compared to those treated with alendronate.

Contraindications: **EVENTITY®** is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating therapy with **EVENTITY®**. **EVENTITY®** is contraindicated in patients with a history of systemic hypersensitivity to romosozumab or to any component of the product formulation. Reactions have included angioedema, erythema multiforme, and urticaria.

Hypersensitivity: Hypersensitivity reactions, including angioedema, erythema multiforme, dermatitis, rash, and urticaria have occurred in **EVENTITY®**-treated patients. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of **EVENTITY®**.

Hypocalcemia: Hypocalcemia has occurred in patients receiving **EVENTITY®**. Correct hypocalcemia prior to initiating **EVENTITY®**. Monitor patients for signs and symptoms of hypocalcemia, particularly in patients with severe renal impairment or receiving dialysis. Adequately supplement patients with calcium and vitamin D while on **EVENTITY®**.

Osteonecrosis of the Jaw (ONJ): ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving **EVENTITY®**. A routine oral exam should be performed by the prescriber prior to initiation of **EVENTITY®**. Concomitant administration of drugs associated with ONJ (chemotherapy, bisphosphonates, denosumab, angiogenesis inhibitors, and corticosteroids) may increase the risk of developing ONJ. Other risk factors for ONJ include cancer, radiotherapy, poor oral hygiene, pre-existing dental disease or infection, anemia, and coagulopathy.

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. In these patients, dental surgery to treat ONJ may exacerbate the condition. Discontinuation of **EVENTITY®** should be considered based on benefit-risk assessment.

Atypical Femoral Fractures: Atypical low-energy or low trauma fractures of the femoral shaft have been reported in patients receiving **EVENTITY®**. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated.

During **EVENTITY®** 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 evaluated to rule out an incomplete femur fracture. Interruption of **EVENTITY®** therapy should be considered based on benefit-risk assessment.

Adverse Reactions: The most common adverse reactions (≥ 5%) reported with **EVENTITY®** were arthralgia and headache.

EVENTITY® is a humanized monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.



Please scan the QR code or visit www.eventity.com/PI for **EVENTITY®** full Prescribing Information, including Boxed Warning and Medication Guide.

BUSINESS CARD
CLEAR SLEEVE



One Amgen Center Drive
Thousand Oaks, CA 91320-1799
www.amgen.com

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EVENTITY®
(romosozumab-aqqg)
injection 105 mg/1.17 mL

EVENTITY®

CODING AND BILLING
INFORMATION GUIDE



FOR PHYSICIAN OFFICES USING THE CMS 1500



FOR HOSPITALS/INSTITUTIONS USING THE CMS 1450

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For 340B Entities: Beginning January 1, 2023, Medicare requires that all claims submitted by 340B covered entities on OPPS claims (bill type 13X) for separately payable Part B drugs and biologicals must include modifiers “JG” (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) or “TB” (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) on claim lines for drugs acquired through the 340B Drug Discount Program. Additional provider types will be required to use these modifiers in 2024.



AMGEN Support⁺

Call Amgen® SupportPlus at 1-866-264-2778 Monday – Friday, 9:00 am – 8:00 pm ET.
Visit AmgenSupportPlus.com to learn how Amgen can help.

INDICATION

EVENTITY® is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

The anabolic effect of **EVENTITY®** wanes after 12 monthly doses of therapy. Therefore, the duration of **EVENTITY®** use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an antiresorptive agent should be considered.

IMPORTANT SAFETY INFORMATION

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Please see additional Important Safety Information on the back cover.



EVENTITY®
(romosozumab-aqqg)
injection 105 mg/1.17 mL



EVENITY® (romosozumab-aqqg) Coding Information

Additional Claim Information in Box 19: (Electronic Form: Loop 2300, or 2400, NTE, 02)	EVENITY® (romosozumab-aqqg), 210 mg
Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01–2)	HCPCS code (J-code): J3111 (injection, romosozumab-aqqg, 1 mg) Select the appropriate NDC from the following as seen on the product carton: NDC number: 55513-880-02 NDC number: 55513-998-02
JW/JZ Modifier	Medicare Part B claims require the use of a JW or JZ modifier for single-dose containers to report discarded or no discarded drug amounts. JW Modifier: Drug amount discarded/not administered to any patient OR JZ Modifier: No discarded amounts 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 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.*
Number of Units in Box 24G: (Electronic Form: Loop 2400, SV1, 04 [03=UN])	Indicate 210 units for one kit. Each EVENITY® kit contains one dose, which is 2 injections for a total dose of 210 mg. The NDC number covers both injections.

Administration and Professional Service Coding Information†

Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01–2)	Healthcare providers should consult the payer or Medicare contractor to determine the code most appropriate for administration. It is the provider's responsibility to ensure that codes used are consistent with payer policy and reflect the service performed. <ul style="list-style-type: none">Determine appropriate product administration CPT code.Relevant evaluation and management (E&M) code. Note when an E&M service is billed in addition to other professional services, the following modifier may be required to distinguish it as a separate service: –25 (significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service)
Considerations:	Each EVENITY® kit contains one dose, which is 2 injections for a total dose of 210 mg. Applicable codes cover both injections.

Diagnosis Code Information†

ICD-10-CM Code in Box 21: (Electronic Form: Loop 2300, HI, 01–2)	The following primary ICD-10-CM diagnosis code may be appropriate to describe patients with current osteoporotic fracture treated with EVENITY®: <ul style="list-style-type: none">M80.0 __ (Age-related osteoporosis with current pathological fracture)<ul style="list-style-type: none">To ensure specificity, 3 additional characters should follow M80.0 to describe laterality, anatomic site, and encounter type See page 6 for coding details for patients with current osteoporotic fracture.
	The following primary diagnosis code may be appropriate to describe patients without current osteoporotic fracture treated with EVENITY®: <ul style="list-style-type: none">M81.0 (Age-related osteoporosis without current pathological fracture)
	The following secondary diagnosis code may be appropriate to describe patients with a personal history of healed osteoporosis fracture: <ul style="list-style-type: none">Z87.310 Personal history of healed osteoporosis fracture

- For postmenopausal women with osteoporosis who are diagnosed as intolerant to other available osteoporosis therapies, consult the ICD-10-CM codes.

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

†The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for EVENITY®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

2 Please see Important Safety Information on the back cover.

Hypothetical Scenarios Illustrating Specificity of M80.0 __ ICD-10-CM Codes*

CLINICAL DIAGNOSIS DETAILS POTENTIAL ICD-10-CM CODE

- Postmenopausal osteoporosis
- Vertebral fractures
- Encounter for evaluating and continuing treatment for the fractures

Age-related osteoporosis with current pathological fracture

M80.08XA

Initial encounter for fracture

Fracture of vertebrae

CLINICAL DIAGNOSIS DETAILS POTENTIAL ICD-10-CM CODE

- Postmenopausal osteoporosis
- Fracture of left wrist
- Follow-up encounter for routine fracture management (after active treatment has been completed)

Age-related osteoporosis with current pathological fracture

M80.032D

Subsequent encounter for fracture with routine healing

Fracture of forearm Left

*The diagnosis code examples and the hypothetical scenarios above are informational and should not be a substitute for an independent clinical decision. They are not intended to be directive or a guarantee of reimbursement. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient, is always the responsibility of the provider or physician. Please contact your payer with any questions.





Examples of ICD-10-CM Codes Relevant for Patients With Current Osteoporotic Fracture Treated With EVENITY® (romosozumab-aqqg)

Age-related osteoporosis with current pathological fracture

➤ **M80.0__** (laterality) (anatomic site) (encounter type)*

Encounter Type[†]

Anatomic Site and Laterality	Initial encounter for fracture	Subsequent encounter for fracture with routine healing	Subsequent encounter for fracture with delayed healing	Subsequent encounter for fracture with nonunion	Subsequent encounter for fracture with malunion	Sequela
UNSPECIFIED SITE	M80.00XA	M80.00XD	M80.00XG	M80.00XK	M80.00XP	M80.00XS
SHOULDER						
Right	M80.011A	M80.011D	M80.011G	M80.011K	M80.011P	M80.011S
Left	M80.012A	M80.012D	M80.012G	M80.012K	M80.012P	M80.012S
Unspecified	M80.019A	M80.019D	M80.019G	M80.019K	M80.019P	M80.019S
HUMERUS						
Right	M80.021A	M80.021D	M80.021G	M80.021K	M80.021P	M80.021S
Left	M80.022A	M80.022D	M80.022G	M80.022K	M80.022P	M80.022S
Unspecified	M80.029A	M80.029D	M80.029G	M80.029K	M80.029P	M80.029S
FOREARM						
Right	M80.031A	M80.031D	M80.031G	M80.031K	M80.031P	M80.031S
Left	M80.032A	M80.032D	M80.032G	M80.032K	M80.032P	M80.032S
Unspecified	M80.039A	M80.039D	M80.039G	M80.039K	M80.039P	M80.039S
HAND						
Right	M80.041A	M80.041D	M80.041G	M80.041K	M80.041P	M80.041S
Left	M80.042A	M80.042D	M80.042G	M80.042K	M80.042P	M80.042S
Unspecified	M80.049A	M80.049D	M80.049G	M80.049K	M80.049P	M80.049S
FEMUR†						
Right	M80.051A	M80.051D	M80.051G	M80.051K	M80.051P	M80.051S
Left	M80.052A	M80.052D	M80.052G	M80.052K	M80.052P	M80.052S
Unspecified	M80.059A	M80.059D	M80.059G	M80.059K	M80.059P	M80.059S
LOWER LEG						
Right	M80.061A	M80.061D	M80.061G	M80.061K	M80.061P	M80.061S
Left	M80.062A	M80.062D	M80.062G	M80.062K	M80.062P	M80.062S
Unspecified	M80.069A	M80.069D	M80.069G	M80.069K	M80.069P	M80.069S
ANKLE AND FOOT						
Right	M80.071A	M80.071D	M80.071G	M80.071K	M80.071P	M80.071S
Left	M80.072A	M80.072D	M80.072G	M80.072K	M80.072P	M80.072S
Unspecified	M80.079A	M80.079D	M80.079G	M80.079K	M80.079P	M80.079S
PELVIS						
Right	M80.0B1A	M80.0B1D	M80.0B1G	M90.0B1K	M80.0B1P	M80.0B1S
Left	M80.0B2A	M80.0B2D	M80.0B2G	M80.0B2K	M80.0B2P	M80.0B2S
Unspecified	M80.0B9A	M80.0B9D	M80.0B9G	M80.0B9K	M80.0B9P	M80.0B9S
VERTEBRA(E)	M80.08XA	M80.08XD	M80.08XG	M80.08XK	M80.08XP	M80.08XS
OTHER SITE	M80.0AXA	M80.0AXD	M80.0AXG	M80.0AXK	M80.0AXP	M80.0AXS

*According to the ICD-10-CM Official Guidelines for Coding and Reporting, M80.0 codes are for patients who have a current pathologic fracture at the time of an encounter. The codes under M80 identify the site of the fracture. A code from category M80, not a traumatic fracture code, should be used for any patient with known osteoporosis who suffers a fracture, even if the patient had a minor fall or trauma, if that fall or trauma would not usually break a normal, healthy bone.

^aAccording to the ICD-10-CM Official Guidelines for Coding and Reporting, seventh character A is for use as long as the patient is receiving active treatment for the fracture. Assignment of the seventh character is based on whether the patient is undergoing active treatment and not whether the provider is seeing the patient for the first time. Seventh character D is to be used for encounters after the patient has completed active treatment. The other seventh characters, listed under each subcategory in the Tabular List, are to be used for subsequent encounters for treatment of problems associated with healing, such as malunions, nonunions, and sequelae.

[‡]Osteoporotic fracture of femur is the approximate synonym of osteoporotic fracture of the hip.

Completing the CMS 1500 for Physician Offices

HEALTH INSURANCE CLAIM FORM

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

PICA										PICA									
1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA BLK LUNG OTHER (Medicare#) (Medicaid#) (ID#/DoD#) (Member ID#) <input checked="" type="checkbox"/> (ID#) <input type="checkbox"/> (ID#)										1a. INSURED'S I.D. NUMBER (For Program in Item 1) XXX-XX-XXXX									
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Doe, Jane J										3. PATIENT'S BIRTH DATE SEX MM DD YY 07 01 1950 M <input type="checkbox"/> F <input checked="" type="checkbox"/>									
5. PATIENT'S ADDRESS (No., Street) 1123 Main Street										4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, Jane J									
6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>										7. INSURED'S ADDRESS (No., Street)									
CITY Hometown STATE MA										CITY STATE									
ZIP CODE 01234 TELEPHONE (Include Area Code) (XXX) XXX-XXXX										ZIP CODE TELEPHONE (Include Area Code) ()									
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)										11. INSURED'S POLICY GROUP OR FECA NUMBER 11111									
a. OTHER INSURED'S POLICY OR GROUP NUMBER										a. INSURED'S DATE OF BIRTH SEX MM DD YY 07 01 1950 M <input type="checkbox"/> F <input checked="" type="checkbox"/>									
b. RESERVED FOR NUCC USE										b. OTHER CLAIM ID (Designated by NUCC) ABC Employer									
c. RESERVED FOR NUCC USE										c. INSURANCE PLAN NAME OR PROGRAM NAME									
10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO b. AUTO ACCIDENT? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO PLACE (State) c. OTHER ACCIDENT?										12. SIGNATURE FROM 18. HOSPITALIZATION FROM 20. OUTSIDE LAB <input type="checkbox"/> YES 22. RESUBMISSION CODE 23. PRIOR AUTHORIZATION NUMBER									
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) EVENTITY® (romosozumab-aqqg), 210 mg										24. A. DATE(S) OF SERVICE From To MM DD YY MM DD YY 01 23 21 01 23 21									
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) M80.0XXX										24. B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER J3111 XX									
24. E. DIAGNOSIS POINTER XXX XX										24. F. \$ CHARGES XXX XX									
24. G. DAYS OR UNITS 210										24. H. EPSDT (Family Plan) 1									
24. I. ID. QUAL. NPI										24. J. RENDERING PROVIDER ID. # NPI									
24. K. RESVD FOR NUCC USE										24. L. RESVD FOR NUCC USE									
24. M. RESVD FOR NUCC USE										24. N. RESVD FOR NUCC USE									
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24. AO. RESVD FOR NUCC USE										24. AP. RESVD FOR NUCC USE									
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24. CJ. RESVD FOR NUCC USE										24. CJ. RESVD FOR NUCC USE									
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24. CN. RESVD FOR NUCC USE										24. CN. RESVD FOR NUCC USE									
24. CO. RESVD FOR NUCC USE										24. CO. RESVD FOR NUCC USE									
24. CP. RESVD FOR NUCC USE										24. CP. RESVD FOR NUCC USE									
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24																			



Completing the CMS 1450 Form for Hospitals

Diagnosis/Condition Code Information [†]	
Revenue Code:	N/A
	Appropriate ICD-10-CM code(s) for patient condition.
	Sequencing of codes may vary based on patient's condition and payer's policy.
	The following primary ICD-10-CM diagnosis code may be appropriate to describe patients with current osteoporotic fracture treated with EVENITY®:
	<ul style="list-style-type: none"> • M80.0_ _ (Age-related osteoporosis with current pathological fracture) <ul style="list-style-type: none"> - To ensure specificity, 3 additional characters should follow M80.0 to describe laterality, anatomic site, and encounter type
	See page 6 for coding details for patients with current osteoporotic fracture.
	The following primary ICD-10-CM diagnosis code may be appropriate to describe patients without current osteoporotic fracture treated with EVENITY®:
	<ul style="list-style-type: none"> • M81.0 (Age-related osteoporosis without current pathological fracture)

- 4 Please see Important Safety Information on the back cover.**

HOSPITALS/INSTITUTIONS (CMS 1450)

EVENITY®

CODING AND BILLING INFORMATION GUIDE



FOR PHYSICIAN OFFICES USING THE CMS 1500



FOR HOSPITALS/INSTITUTIONS USING THE CMS 1450

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AMGEN® Support+

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The anabolic effect of EVENITY® wanes after 12 monthly doses of therapy. Therefore, the duration of EVENITY® use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an antiresorptive agent should be considered.

IMPORTANT SAFETY INFORMATION

POTENTIAL RISK OF MYOCARDIAL INFARCTION, STROKE, AND CARDIOVASCULAR DEATH

EVENITY® may increase the risk of myocardial infarction, stroke and cardiovascular death. EVENITY® should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. Monitor for signs and symptoms of myocardial infarction and stroke and instruct patients to seek prompt medical attention if symptoms occur. If a patient experiences a myocardial infarction or stroke during therapy, EVENITY® should be discontinued.

Please see Important Safety Information on page 8.



EVENITY®
(romosozumab-aqqg)
injection 105 mg/1.17 mL



EVENTITY® (romosozumab-aqqg) Coding Information

Additional Claim Information in Box 19: (Electronic Form: Loop 2300, or 2400, NTE, 02)	EVENTITY® (romosozumab-aqqg), 210 mg
Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)	HCPCS code (J-code): J3111 (injection, romosozumab-aqqg, 1 mg) Select the appropriate NDC from the following as seen on the product carton: NDC number: 55513-880-02 NDC number: 55513-998-02 Medicare Part B claims require the use of a JW or JZ modifier for single-dose containers to report discarded or no discarded drug amounts. JW Modifier: Drug amount discarded/not administered to any patient OR JZ Modifier: No discarded amounts 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 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.*
Number of Units in Box 24G: (Electronic Form: Loop 2400, SV1, 04 [03=UN])	Indicate 210 units for one kit. Each EVENTITY® kit contains one dose, which is 2 injections for a total dose of 210 mg. The NDC number covers both injections.

Administration and Professional Service Coding Information†

Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)	Healthcare providers should consult the payer or Medicare contractor to determine the code most appropriate for administration. It is the provider's responsibility to ensure that codes used are consistent with payer policy and reflect the service performed. <ul style="list-style-type: none"> Determine appropriate product administration CPT code. Relevant evaluation and management (E&M) code. Note when an E&M service is billed in addition to other professional services, the following modifier may be required to distinguish it as a separate service: -25 (significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service)
Considerations:	Each EVENTITY® kit contains one dose, which is 2 injections for a total dose of 210 mg. Applicable codes cover both injections.

Diagnosis Code Information†

ICD-10-CM Code in Box 21: (Electronic Form: Loop 2300, HI, 01-2)	The following primary ICD-10-CM diagnosis code may be appropriate to describe patients with current osteoporotic fracture treated with EVENTITY®: <ul style="list-style-type: none"> M80.0 _ _ (Age-related osteoporosis with current pathological fracture) <ul style="list-style-type: none"> To ensure specificity, 3 additional characters should follow M80.0 to describe laterality, anatomic site, and encounter type See page 6 for coding details for patients with current osteoporotic fracture.
	The following primary diagnosis code may be appropriate to describe patients without current osteoporotic fracture treated with EVENTITY®: <ul style="list-style-type: none"> M81.0 (Age-related osteoporosis without current pathological fracture)
	The following secondary diagnosis code may be appropriate to describe patients with a personal history of healed osteoporosis fracture: <ul style="list-style-type: none"> Z87.310 Personal history of healed osteoporosis fracture


- For postmenopausal women with osteoporosis who are diagnosed as intolerant to other available osteoporosis therapies, consult the ICD-10-CM codes.

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

†The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for EVENTITY®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Please see Important Safety Information on page 8.

Completing the CMS 1500 for Physician Offices



HEALTH INSURANCE CLAIM FORM

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

CARRIER

☐ PICA

1. MEDICARE ☐ MEDICAID ☐ TRICARE ☐ CHAMPVA ☐ GROUP HEALTH PLAN ☒ FECA BLK LUNG ☐ OTHER ☐

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
Doe, Jane J

3. PATIENT'S BIRTH DATE
MM DD YY
07 01 1950 SEX ☐ M ☒ F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)
Doe, Jane J

5. PATIENT'S ADDRESS (No., Street)
1123 Main Street

6. PATIENT RELATIONSHIP TO INSURED
Self ☐ Spouse ☐ Child ☐ Other ☐

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

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

a. EMPLOYMENT? (Current or Previous)
☐ YES ☒ NO

b. AUTO ACCIDENT?
☐ YES ☒ NO

c. OTHER ACCIDENT?

11. INSURED'S POLICY GROUP OR FECA NUMBER
11111

a. INSURED'S DATE OF BIRTH
MM DD YY
07 01 1950 SEX ☐ M ☒ F

b. OTHER CLAIM ID (Designated by NUCC)
ABC Employer

c. INSURANCE PLAN NAME OR PROGRAM NAME

12. CITY
Hometown

13. STATE
MA

14. ZIP CODE
01234

15. TELEPHONE (Include Area Code)
(XXX) XXX-XXXX

16. SIGNATURE
DATE
07-01-23

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

18. HOSPITALIZATION
FROM
TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
EVENTITY® (romosozumab-aqqg), 210 mg

20. OUTSIDE LABORATORY
☐ YES ☒ NO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD-10 CM code
M80.0XXX

22. RESUBMISSION CODE

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE C. D. PROCEDURES, SERVICES, OR SUPPLIES E. DIAGNOSIS POINTER F. CHARGES G. DAYS OR UNITS H. EPSDT Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #

1. **01 23 21 01 23 21 11 J3111 XX XXX XX 210 NPI**

2. **21 11 96XXX XXX XX 1 NPI**

SIGNED **07-01-23** DATE a. **XXXXXXXXXX** b. **XXXXXXXXXX**

Hometown, MA 01234

a. **XXXXXXXXXX** b. **XXXXXXXXXX**

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

(BOX 19) ADDITIONAL CLAIM INFORMATION:

Indicate EVENITY® (romosozumab-aqqg), 210 mg. If required by the payer, enter additional information such as the NDC.

(BOX 21) DIAGNOSIS OR NATURE OF ILLNESS OR INJURY:

Indicate appropriate ICD diagnosis code as reflected in the patient's medical record. ICD-10 CM code example: M80.0 (Age-related osteoporosis with current pathological fracture).

(BOX 23) PRIOR AUTHORIZATION NUMBER (IF APPLICABLE)

(BOX 24G) DAYS OR UNITS:

Indicate 210 units for one kit. Each EVENITY® kit contains one dose, which is 2 injections.

(BOX 24A) SHADED BOX:

If NDC reporting is required (i.e., for Medicaid and some commercial payers), enter NDC for EVENITY® in shaded portion of Item 24A above the date of service. Check with the payer to determine the proper format for NDC reporting.

(BOX 24D) PROCEDURES, SERVICES, OR SUPPLIES:

Product

Use J3111 (injection, romosozumab-aqqg, 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).

Related Administration Procedure

Determine appropriate product administration CPT code.

Please note: Each EVENITY® kit contains one dose, which is 2 injections. Applicable codes cover both injections. Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of EVENITY®.



EVENTITY® (romosozumab-aqqg) Coding Information

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)	Medicare: 0636 , drugs requiring detailed coding. Other Payers: 0250 , general pharmacy; OR 0636 , if required by a given payer.
Coding Information in Box 44: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])	HCPCS Code (J-Code): J3111 (injection, romosozumab-aqqg, 1 mg) Select the appropriate NDC from the following as seen on the product carton: NDC number: 55513-880-02 NDC number: 55513-998-02
JW/JZ Modifier	Medicare Part B claims require the use of a JW or JZ modifier for single-dose containers to report discarded or no discarded drug amounts. JW Modifier: Drug amount discarded/not administered to any patient OR JZ Modifier: No discarded amounts 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 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.*
Service Units in Box 46: (Electronic Form: Loop 2400, SV205)	Indicate 210 units for one kit. Each EVENTITY® kit contains one dose, which is 2 injections for a total dose of 210 mg. The NDC number covers both injections.

Administration Coding Information†

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)	Appropriate revenue code for the cost center in which the service is performed.
Description in Box 43: (Not required by Medicare)	Indicate drug name and unit of measure, for example, EVENTITY® 210 mg.
Coding Information in Box 44: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])	Healthcare providers should consult the payer or Medicare contractor to determine the code most appropriate for administration. It is the provider's responsibility to ensure that codes used are consistent with payer policy and reflect the service performed. <ul style="list-style-type: none"> Determine appropriate product administration CPT code. Relevant evaluation and management (E&M) code. Note when an E&M service is billed in addition to other professional services, the following modifier may be required to distinguish it as a separate service: -25 (significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service)
Considerations:	Each EVENTITY® kit contains one dose, which is 2 injections for a total dose of 210 mg. Applicable codes cover both injections.

Diagnosis/Condition Code Information†

Revenue Code:	N/A
ICD-10-CM Code in Box 66: (Electronic Form: Loop 2300, HI01-2 [HI01-1=BK])	Appropriate ICD-10-CM code(s) for patient condition. Sequencing of codes may vary based on patient's condition and payer's policy. The following primary ICD-10-CM diagnosis code may be appropriate to describe patients with current osteoporotic fracture treated with EVENTITY®: <ul style="list-style-type: none"> M80.0 __ (Age-related osteoporosis with current pathological fracture) <ul style="list-style-type: none"> To ensure specificity, 3 additional characters should follow M80.0 to describe laterality, anatomic site, and encounter type See page 6 for coding details for patients with current osteoporotic fracture. The following primary ICD-10-CM diagnosis code may be appropriate to describe patients without current osteoporotic fracture treated with EVENTITY®: <ul style="list-style-type: none"> M81.0 (Age-related osteoporosis without current pathological fracture)

- For postmenopausal women with osteoporosis who are diagnosed as intolerant to other available osteoporosis therapies, consult the ICD-10-CM codes.

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

†The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for EVENTITY®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Please see Important Safety Information on page 8.

Completing the CMS 1450 Form for Hospitals



1 Anytown Hospital 100 Main Street Anytown, Anystate 01010		2		3a PAT. CNTL. #		4 TYPE OF BILL	
5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM		7 THROUGH			
8 PATIENT NAME a Smith, James		9 PATIENT ADDRESS a 123 Main Street, Anytown, Anystate 12345					
b		c		d		e	
STAT 18 19		26 27 28		29 ACCT STATE		30	
CODE		OCCURRENCE DATE		40 CC			
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	
1 0636		EVENITY® 210 mg		J3111-XX		MMDYY	
2 0510		Clinic		96XXX		MMDYY	
3							
46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49	
210		XXXXXX					
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B							
C							
54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57	
						OTHER	
						PRV ID	
58 REL.		60 INSURED'S UNIQUE ID		61 GROUP NAME		62 INSURANCE GROUP NO.	
64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME					
66 DX		M80.0XXX		68			
69 ADMIT DX		70 PATIENT		71 PBS		72	
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80 REMARKS		81CC a		82		83	
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Examples of ICD-10-CM Codes Relevant for Patients With Current Osteoporotic Fracture Treated With EVENITY® (romosozumab-aqqg)

Age-related osteoporosis with current pathological fracture

➤ **M80.0__** (laterality) (anatomic site) (encounter type)*

Encounter Type[†]

Anatomic Site and Laterality	Initial encounter for fracture	Subsequent encounter for fracture with routine healing	Subsequent encounter for fracture with delayed healing	Subsequent encounter for fracture with nonunion	Subsequent encounter for fracture with malunion	Sequela
UNSPECIFIED SITE	M80.00XA	M80.00XD	M80.00XG	M80.00XK	M80.00XP	M80.00XS
SHOULDER						
Right	M80.011A	M80.011D	M80.011G	M80.011K	M80.011P	M80.011S
Left	M80.012A	M80.012D	M80.012G	M80.012K	M80.012P	M80.012S
Unspecified	M80.019A	M80.019D	M80.019G	M80.019K	M80.019P	M80.019S
HUMERUS						
Right	M80.021A	M80.021D	M80.021G	M80.021K	M80.021P	M80.021S
Left	M80.022A	M80.022D	M80.022G	M80.022K	M80.022P	M80.022S
Unspecified	M80.029A	M80.029D	M80.029G	M80.029K	M80.029P	M80.029S
FOREARM						
Right	M80.031A	M80.031D	M80.031G	M80.031K	M80.031P	M80.031S
Left	M80.032A	M80.032D	M80.032G	M80.032K	M80.032P	M80.032S
Unspecified	M80.039A	M80.039D	M80.039G	M80.039K	M80.039P	M80.039S
HAND						
Right	M80.041A	M80.041D	M80.041G	M80.041K	M80.041P	M80.041S
Left	M80.042A	M80.042D	M80.042G	M80.042K	M80.042P	M80.042S
Unspecified	M80.049A	M80.049D	M80.049G	M80.049K	M80.049P	M80.049S
FEMUR[‡]						
Right	M80.051A	M80.051D	M80.051G	M80.051K	M80.051P	M80.051S
Left	M80.052A	M80.052D	M80.052G	M80.052K	M80.052P	M80.052S
Unspecified	M80.059A	M80.059D	M80.059G	M80.059K	M80.059P	M80.059S
LOWER LEG						
Right	M80.061A	M80.061D	M80.061G	M80.061K	M80.061P	M80.061S
Left	M80.062A	M80.062D	M80.062G	M80.062K	M80.062P	M80.062S
Unspecified	M80.069A	M80.069D	M80.069G	M80.069K	M80.069P	M80.069S
ANKLE AND FOOT						
Right	M80.071A	M80.071D	M80.071G	M80.071K	M80.071P	M80.071S
Left	M80.072A	M80.072D	M80.072G	M80.072K	M80.072P	M80.072S
Unspecified	M80.079A	M80.079D	M80.079G	M80.079K	M80.079P	M80.079S
PELVIS						
Right	M80.0B1A	M80.0B1D	M80.0B1G	M90.0B1K	M80.0B1P	M80.0B1S
Left	M80.0B2A	M80.0B2D	M80.0B2G	M80.0B2K	M80.0B2P	M80.0B2S
Unspecified	M80.0B9A	M80.0B9D	M80.0B9G	M80.0B9K	M80.0B9P	M80.0B9S
VERTEBRA(E)	M80.08XA	M80.08XD	M80.08XG	M80.08XK	M80.08XP	M80.08XS
OTHER SITE	M80.0AXA	M80.0AXD	M80.0AXG	M80.0AXK	M80.0AXP	M80.0AXS

*According to the ICD-10-CM Official Guidelines for Coding and Reporting, M80.0 codes are for patients who have a current pathologic fracture at the time of an encounter. The codes under M80 identify the site of the fracture. A code from category M80, not a traumatic fracture code, should be used for any patient with known osteoporosis who suffers a fracture, even if the patient had a minor fall or trauma, if that fall or trauma would not usually break a normal, healthy bone.

[†]According to the ICD-10-CM Official Guidelines for Coding and Reporting, seventh character A is for use as long as the patient is receiving active treatment for the fracture. Assignment of the seventh character is based on whether the patient is undergoing active treatment and not whether the provider is seeing the patient for the first time. Seventh character D is to be used for encounters after the patient has completed active treatment. The other seventh characters, listed under each subcategory in the Tabular List, are to be used for subsequent encounters for treatment of problems associated with healing, such as malunions, nonunions, and sequelae.

[‡]Osteoporotic fracture of femur is the approximate synonym of osteoporotic fracture of the hip.

Please see Important Safety Information on page 8.

Hypothetical Scenarios Illustrating Specificity of M80.0__ ICD-10-CM Codes*

CLINICAL DIAGNOSIS DETAILS POTENTIAL ICD-10-CM CODE

- Postmenopausal osteoporosis
- Vertebral fractures
- Encounter for evaluating and continuing treatment for the fractures

Age-related osteoporosis with current pathological fracture

M80.08XA

Initial encounter for fracture

Fracture of vertebrae

CLINICAL DIAGNOSIS DETAILS POTENTIAL ICD-10-CM CODE

- Postmenopausal osteoporosis
- Fracture of left wrist
- Follow-up encounter for routine fracture management (after active treatment has been completed)

Age-related osteoporosis with current pathological fracture

M80.032D

Subsequent encounter for fracture with routine healing

Fracture of forearm

Left

*The diagnosis code examples and the hypothetical scenarios above are informational and should not be a substitute for an independent clinical decision. They are not intended to be directive or a guarantee of reimbursement. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient, is always the responsibility of the provider or physician. Please contact your payer with any questions.

Considerations
for Complete
Claim Submission

CORRECT AND COMPLETE PATIENT
INFORMATION:

- ☐ Patient name
 - ID number
 - Health insurer name and/or group number
- ☐ Provider name
 - National provider ID number
 - Contact information

COLLECT PRODUCT AND BILLING INFORMATION:

- ☐ CPT/HCPCS code (J-Code) and units
- ☐ Determine appropriate JW or JZ modifier
- ☐ Diagnosis code to the highest level of specificity
 - Primary diagnosis code
- ☐ Identify appropriate administration code
- ☐ Determine prior authorization criteria (if required)
- ☐ Medicaid and commercial payers may require NDC reporting

SUPPLEMENTAL DOCUMENTATION
CONSIDERATIONS (INCLUDING TEST
RESULTS AND DATE AS APPROPRIATE):

- ☐ Original diagnostic T-score and/or FRAX predicted fracture risk
- ☐ Previous therapies
 - Reason for discontinuations
- ☐ Calcium and Vitamin D
- ☐ Prior osteoporosis-related fracture history
 - Location of fracture (provide ICD-10 number[s])
- ☐ Referring physician orders
- ☐ Risk factors for fracture
- ☐ Cardiovascular risk assessment
 - Confirm patients had no myocardial infarction or stroke events within the last 12 months

CONFIRM BILLING AND PAYER REQUIREMENTS:

- ☐ Omit or include punctuation as required in submitted claims
- ☐ Follow required time frame for submission after rendering service

ICD-10 – CM CODE EXAMPLES

Important Safety Information

POTENTIAL RISK OF MYOCARDIAL INFARCTION, STROKE, AND CARDIOVASCULAR DEATH

EVENTITY® may increase the risk of myocardial infarction, stroke and cardiovascular death. **EVENTITY®** should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. Monitor for signs and symptoms of myocardial infarction and stroke and instruct patients to seek prompt medical attention if symptoms occur. If a patient experiences a myocardial infarction or stroke during therapy, **EVENTITY®** should be discontinued.

In a randomized controlled trial in postmenopausal women, there was a higher rate of major adverse cardiac events (MACE), a composite endpoint of cardiovascular death, nonfatal myocardial infarction and nonfatal stroke, in patients treated with **EVENTITY®** compared to those treated with alendronate.

Contraindications: **EVENTITY®** is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating therapy with **EVENTITY®**. **EVENTITY®** is contraindicated in patients with a history of systemic hypersensitivity to romosozumab or to any component of the product formulation. Reactions have included angioedema, erythema multiforme, and urticaria.

Hypersensitivity: Hypersensitivity reactions, including angioedema, erythema multiforme, dermatitis, rash, and urticaria have occurred in **EVENTITY®**-treated patients. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of **EVENTITY®**.

Hypocalcemia: Hypocalcemia has occurred in patients receiving **EVENTITY®**. Correct hypocalcemia prior to initiating **EVENTITY®**. Monitor patients for signs and symptoms of hypocalcemia, particularly in patients with severe renal impairment or receiving dialysis. Adequately supplement patients with calcium and vitamin D while on **EVENTITY®**.

Osteonecrosis of the Jaw (ONJ): ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving **EVENTITY®**. A routine oral exam should be performed by the prescriber prior to initiation of **EVENTITY®**. Concomitant administration of drugs associated with ONJ (chemotherapy, bisphosphonates, denosumab, angiogenesis inhibitors, and corticosteroids) may increase the risk of developing ONJ. Other risk factors for ONJ include cancer, radiotherapy, poor oral hygiene, pre-existing dental disease or infection, anemia, and coagulopathy.

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. In these patients, dental surgery to treat ONJ may exacerbate the condition. Discontinuation of **EVENTITY®** should be considered based on benefit-risk assessment.

Atypical Femoral Fractures: Atypical low-energy or low trauma fractures of the femoral shaft have been reported in patients receiving **EVENTITY®**. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated.

During **EVENTITY®** 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 evaluated to rule out an incomplete femur fracture. Interruption of **EVENTITY®** therapy should be considered based on benefit-risk assessment.

Adverse Reactions: The most common adverse reactions (≥ 5%) reported with **EVENTITY®** were arthralgia and headache.

EVENTITY® is a humanized monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

Please see **EVENTITY® full Prescribing Information, including Medication Guide.**



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