YOUR GUIDE TO EVENITY® BILLING AND CODING INFORMATION

FOR PHYSICIAN OFFICES USING THE CMS 1500

FOR HOSPITALS/INSTITUTIONS USING THE CMS 1450

The information provided in this guide is of a general nature and for informational purposes only. Coding and coverage policies change periodically and often without warning. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient and/or procedure, is always the responsibility of the provider or physician. The information provided in this guide should in no way be considered a guarantee of coverage or reimbursement for any product or service.

AMGEN Assist®

Call **Amgen Assist®** for assistance with specific payer requirements:
1-866-AMG-ASST (1-866-264-2778) Monday through Friday, 9:00 am to 8:00 pm ET.

INDICATION

EVENITY® 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 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 additional Important Safety Information on the back cover.

EVENITY®
(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)[1]	EVENITY® (romosozumab-aqqg), 210 mg
Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)[1]	**HCPCS code (J-code): J3111** (injection, romosozumab-aqqg, 1 mg)[2]
Number of Units in Box 24G: (Electronic Form: Loop 2400, SV1, 04 [03=UN])[1]	Indicate 210 units for one kit. Each EVENITY® kit contains one dose, which is 2 injections for a total dose of 210 mg.[3] The NDC number covers both injections.

Administration and Professional Service Coding Information*

Coding Information in Box 24D: (Electronic Form: Loop 2400, SV1, 01-2)[1]	The following code may be available to report administration of EVENITY®. Other codes may be appropriate on a payer-specific basis. It is the provider's responsibility to ensure that codes used are consistent with payer policy and reflect service performed under such codes: • **96372** (therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)[4] • **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.[3] Applicable codes cover both injections.

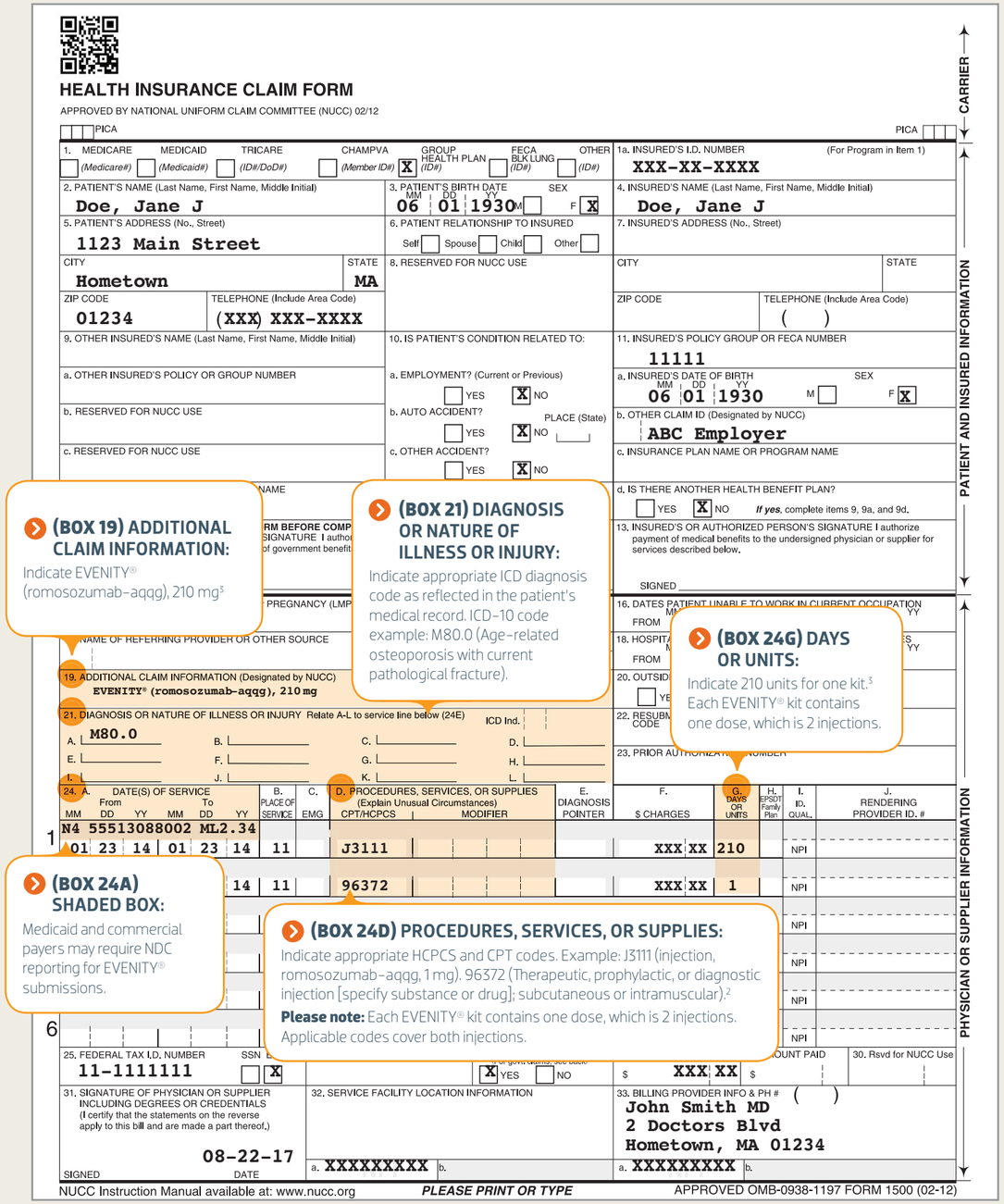
Diagnosis Code Information*

ICD-10-CM Code in Box 21: (Electronic Form: Loop 2300, HI, 01-2)[1]	The following primary ICD-10-CM diagnosis code may be appropriate to describe patients ***with*** current osteoporotic fracture treated with EVENITY®: • **M80.0** (Age-related osteoporosis with current pathological fracture)[5] Please see page 6 for additional examples for patients with current osteoporotic fracture.
	The following primary diagnosis code may be appropriate to describe patients ***without*** current osteoporotic fracture treated with EVENITY®: • **M81.0** (Age-related osteoporosis without current pathological fracture)[5,†]

*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.

†According to the ICD-10-CM Official Guidelines for Coding and Reporting, M81 code is for use with patients with osteoporosis who do not currently have a pathologic fracture due to the osteoporosis, even if they have had a fracture in the past. For patients with a history of osteoporosis fractures, status code Z87.310 (personal history of [healed] osteoporosis fracture) should follow the code from the M81 category.[6]

Call Amgen Assist® for support with billing and coding questions: 1-866-AMG-ASST (1-866-264-2778) Monday through Friday, 9:00 am to 8:00 pm ET.



(BOX 19) ADDITIONAL CLAIM INFORMATION:
Indicate EVENITY® (romosozumab-aqqg), 210 mg[3]

(BOX 21) DIAGNOSIS OR NATURE OF ILLNESS OR INJURY:
Indicate appropriate ICD diagnosis code as reflected in the patient's medical record. ICD-10 code example: M80.0 (Age-related osteoporosis with current pathological fracture).

(BOX 24G) DAYS OR UNITS:
Indicate 210 units for one kit.[3] Each EVENITY® kit contains one dose, which is 2 injections.

(BOX 24A) SHADED BOX:
Medicaid and commercial payers may require NDC reporting for EVENITY® submissions.

(BOX 24D) PROCEDURES, SERVICES, OR SUPPLIES:
Indicate appropriate HCPCS and CPT codes. Example: J3111 (injection, romosozumab-aqqg, 1 mg). 96372 (Therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular).[2]
Please note: Each EVENITY® kit contains one dose, which is 2 injections. Applicable codes cover both injections.

Hospital/Institutional Billing Information

Dimensions: 18"x11"

EVENITY® (romosozumab-aqqg) Coding Information

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)[7]	**Medicare: 0636,** drugs requiring detailed coding.[8] **Other Payers: 0250,** general pharmacy; OR **0636,** if required by a given payer.[8,9]
Coding Information in Box 44: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])[7]	**HCPCS Code (J-Code): J3111** (injection, romosozumab-aqqg, 1 mg)[2]
Service Units in Box 46: (Electronic Form: Loop 2400, SV205)[7]	Indicate 210 units for one kit. Each EVENITY® kit contains one dose, which is 2 injections for a total dose of 210 mg.[3] The NDC number covers both injections.[3]

Administration Coding Information*

Revenue Code in Box 42: (Electronic Form: Loop 2400, SV201)[7]	Appropriate revenue code for the cost center in which the service is performed.
Description in Box 43: (Not required by Medicare)[7]	Indicate drug name and unit of measure, for example, EVENITY® 210 mg.
Coding Information in Box 44: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])[7]	• **96372** (therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular)[4] • **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.[3] 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])[7]	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®: • **M80.0** (Age-related osteoporosis with current pathological fracture)[5] Please see page 6 for additional examples 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®: • **M81.0** (Age-related osteoporosis without current pathological fracture)[5,†]

*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.

†According to the ICD-10-CM Official Guidelines for Coding and Reporting, M81 code is for use with patients with osteoporosis who do not currently have a pathologic fracture due to the osteoporosis, even if they have had a fracture in the past. For patients with a history of osteoporosis fractures, status code Z87.310 (personal history of [healed] osteoporosis fracture) should follow the code from the M81 category.[6]

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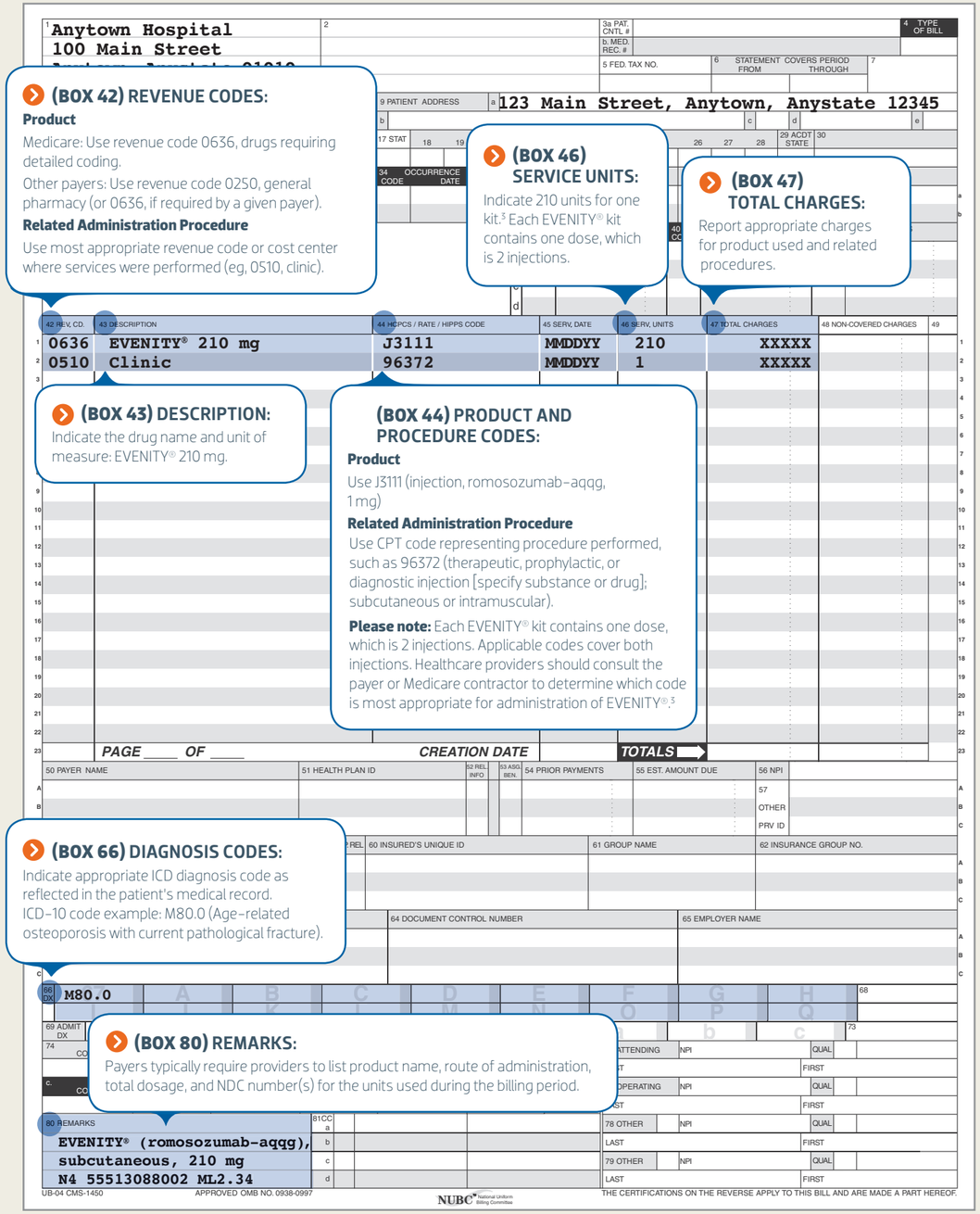
Completing the CMS 1450 Form for Hospitals



(BOX 42) REVENUE CODES:

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 or cost center where services were performed (eg, 0510, clinic).

(BOX 46) SERVICE UNITS:

Indicate 210 units for one kit.[3] Each EVENITY® kit contains one dose, which is 2 injections.

(BOX 47) TOTAL CHARGES:

Report appropriate charges for product used and related procedures.

(BOX 43) DESCRIPTION:

Indicate the drug name and unit of measure: EVENITY® 210 mg.

(BOX 44) PRODUCT AND PROCEDURE CODES:

Product

Use J3111 (injection, romosozumab-aqqg, 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).

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®.[3]

(BOX 66) DIAGNOSIS CODES:

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

(BOX 80) REMARKS:

Payers typically require providers to list product name, route of administration, total dosage, and NDC number(s) for the units used during the billing period.

Examples of ICD-10-CM Codes Relevant for Patients With Current Osteoporotic Fracture Treated With EVENITY®[5]

M80.0___ Age-related osteoporosis with current pathological fracture (laterality) (anatomic site) (encounter type)*

Anatomic Site and Laterality	Encounter Type†					
	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
VERTEBRA(E)	M80.08XA	M80.08XD	M80.08XG	M80.08XK	M80.08XP	M80.08XS

See the next page for hypothetical scenarios illustrating specificity of these M80.0_ _ _ ICD-10-CM codes. The diagnosis code examples above and the hypothetical scenarios on back of the insert 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.

*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.[6]

†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.[6]

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

CLINICAL DIAGNOSIS DETAILS

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

POTENTIAL ICD-10-CM CODE[5]

Age-related osteoporosis with current pathological fracture

M80.08XA

Initial encounter for fracture

Fracture of vertebrae

CLINICAL DIAGNOSIS DETAILS

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

POTENTIAL ICD-10-CM CODE

Age-related osteoporosis with current pathological fracture

Left

M80.032D

Subsequent encounter for fracture with routine healing

Fracture of forearm

References: 1. Palmetto GBA. ASC 837 v5010 to CMS-1500 Crosswalk. http://www.palmettogba.com/Palmetto/Providers.Nsf/files/CMS1500_837v5010_Crosswalk.pdf/$File/CMS1500_837v5010_Crosswalk.pdf. Accessed August 21, 2019. **2.** Centers for Medicare and Medicaid Services. HCPCS Release Code Sets. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/Other-Codes-2019-July-Revised.zip. Accessed August 21, 2019. **3.** EVENITY® (romosozumab-aqqg) prescribing information, Amgen. **4.** American Medical Association. 2017 Professional Edition, Current Procedural Terminology (CPT) copyright 2016 American Medical Association. All rights reserved. **5.** Centers for Disease Control and Prevention. 2019 ICD-10-CM tabular list of diseases and injuries. In: International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM). FY 2019. Full PDF. ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2019/. Accessed August 21, 2019. **6.** CMS. ICD-10-CM official guidelines for coding and reporting, FY 2019. https://www.cdc.gov/nchs/icd/data/10cmguidelines-FY2019-final.pdf. Accessed August 21, 2019. **7.** Palmetto GBA. ASC 837I version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. http://www.palmettogba.com/Palmetto/Providers.Nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf. Accessed August 21, 2019. **8.** Value Healthcare Services. Understanding hospital revenue codes. http://valuehealthcareservices.com/education/understanding-hospital-revenue-codes/. Accessed August 21, 2019. **9.** Centers for Medicare & Medicaid Services. Publication 100-04: Medicare Claims Processing Manual. Chapter 17: drugs and biologicals. Section 80.9: required modifiers for ESAs administered to non-ESRD patients. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf. Accessed August 21, 2019.

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

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:

- ☐ Correct HCPCS code and units
- ☐ 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 levels
- ☐ Prior osteoporosis-related fracture history
  - – Location of fracture (please 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

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.

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 EVENITY® compared to those treated with alendronate.

Contraindications: EVENITY® is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating therapy with EVENITY®. EVENITY® 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 EVENITY®-treated patients. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of EVENITY®.

Hypocalcemia: Hypocalcemia has occurred in patients receiving EVENITY®. Correct hypocalcemia prior to initiating EVENITY®. 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 EVENITY®.

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 EVENITY®. A routine oral exam should be performed by the prescriber prior to initiation of EVENITY®. 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 EVENITY® 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 EVENITY®. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated.

During EVENITY® 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 EVENITY® therapy should be considered based on benefit-risk assessment.

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

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

Please see accompanying EVENITY® full Prescribing Information, including Medication Guide.

AMGEN
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AMGEN Assist®

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