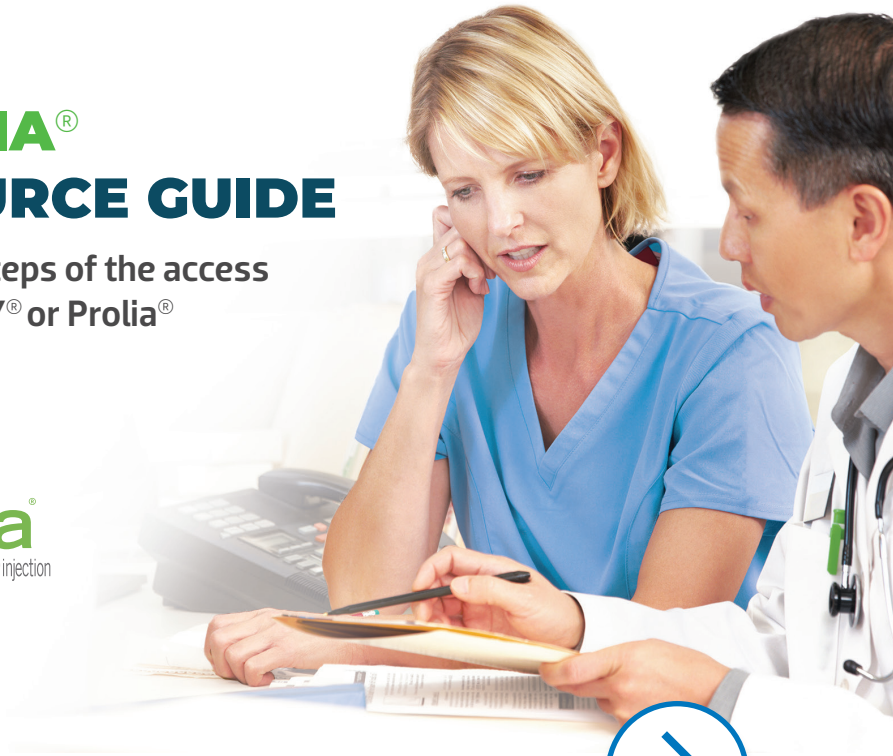
EVENITY® AND PROLIA®
FULFILLMENT RESOURCE GUIDE

A guide to help your office through the steps of the access and reimbursement process for EVENITY® or Prolia®



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

prolia®
(denosumab) injection

EVENITY® 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.

PROLIA® INDICATION

Prolia® is indicated for the treatment of postmenopausal women with osteoporosis 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. In postmenopausal women with osteoporosis, Prolia® reduces the incidence of vertebral, nonvertebral, and hip fractures.

IMPORTANT SAFETY INFORMATION

SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE:

Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following Prolia administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiating Prolia in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with Prolia in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Please see additional EVENITY® Important Safety Information on page 17.
Please see additional Prolia® Important Safety Information on pages 17 and 18.

AMGEN®

ABOUT YOUR OFFICE

Use this sheet to keep track of important information for your office.
Consider using the spaces below to note the names of prescribers and office staff members, as well as contact information for wholesalers, alternate sites of care, and pharmacies.

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.

OFFICE NOTES

CONTACT YOUR AMGEN REPRESENTATIVE:

Amgen sales representative:	
Phone number:	
Email address:	
Amgen Access Specialist:	
Phone number:	

Please see EVENITY® Important Safety Information on page 17.
Please see Prolia® Important Safety Information on pages 17 and 18.

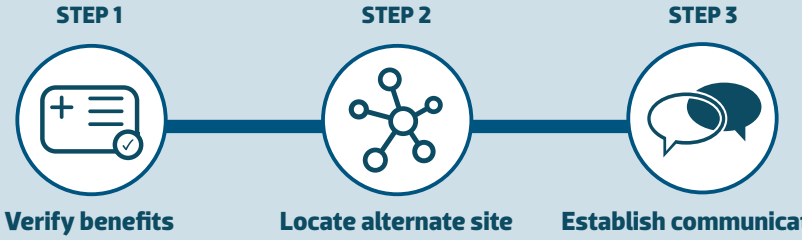
3 FULFILLMENT PATHWAY OPTIONS

In this guide, you'll find the steps to obtaining EVENITY® (romosozumab-aqqg) or Prolia® (denosumab) through each of the fulfillment pathways below and where to access helpful resources for your office.

Refer to **page 19** for definitions of key terms you may see during the fulfillment process.

BUY AND BILL: Purchase EVENITY® or Prolia® directly from a wholesaler and administer in office

REFERRAL TO ALTERNATE SITES OF CARE: Refer patients to a local alternate site of care where EVENITY® or Prolia® can be purchased and administered in office



PHARMACY/SPECIALTY PHARMACY (USING THE PHARMACY BENEFIT FOR PROLIA®): Send the prescription to a pharmacy or specialty pharmacy and administer in office

*Remind your patient that medication should be shipped to your office and not to their home.

Please see EVENITY® Important Safety Information on page 17.
Please see Prolia® Important Safety Information on pages 17 and 18.

AMGEN Support+

SUPPORT FROM Amgen® SupportPlus

Amgen SupportPlus provides personalized support for your office and patients throughout the access and reimbursement process, regardless of which fulfillment pathway you or your office uses to get EVENITY® (romosozumab-aqqg) or Prolia® (denosumab) to your patients.

AMGEN Support+

CONTACT **Amgen SupportPlus** AT 1-866-264-2778, MONDAY THROUGH FRIDAY, 9:00 AM TO 8:00 PM ET, OR VISIT Amgen SupportPlus CUSTOMER PORTAL AT **MYAMGENPORTAL.COM**

Register for Amgen SupportPlus Customer Portal, a tool for managing patient benefits verification and more (See **next page** for more information)

Verify your patient's insurance and review coverage and out-of-pocket costs via a Summary of Benefits document from Amgen SupportPlus

Identify patient financial resources

	Patient's insurance type		
Financial Resource	**Medicare or government program coverage**	**Commercial**	**Uninsured or underinsured**
Courtesy referrals to independent co-pay foundations*	✓		
Amgen SupportPlus Co-Pay Program		✓	
Transfers to Amgen Safety Net Foundation†			✓

*Amgen has no control over these independent charitable patient assistance programs (including their program eligibility and other criteria) and provides transfers as a courtesy only.

†Amgen Safety Net Foundation (ASNF) is a nonprofit patient assistance program sponsored by Amgen that provides EVENITY® or Prolia® at no cost to qualifying patients who have a financial need and who are uninsured or have insurance that excludes EVENITY® or Prolia®.

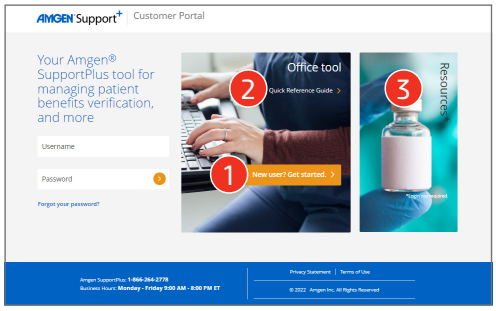
Locate alternate sites of care through **EVENITYFinder.com** or **ProliaFinder.com**

Amgen Access Specialists can provide live or virtual coverage and access resources to support your patients

Please see EVENITY® Important Safety Information on page 17.
Please see Prolia® Important Safety Information on pages 17 and 18.

ONLINE ASSISTANCE THROUGH THE Amgen® SupportPlus CUSTOMER PORTAL

Amgen SupportPlus Customer Portal is a tool for managing patient benefits verification and more. Submit, store, and retrieve benefit verifications electronically.

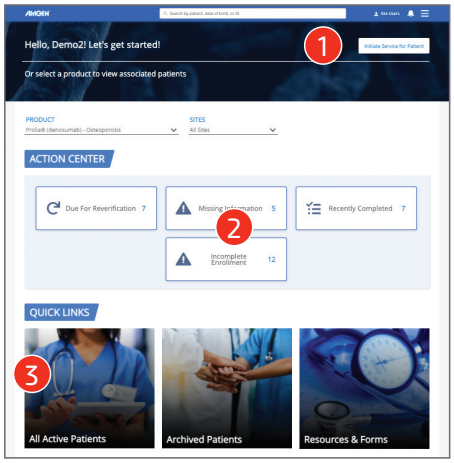


1. **Register for the Amgen SupportPlus Customer Portal** by visiting **MyAmgenPortal.com** and clicking "New user? Get started."
   - You can download the **Amgen SupportPlus Customer Portal Quick Reference Guide** and other **Resources** through the portal's homepage **without login credentials**

   1 New Users start here

   2 Quick Reference Guide found here

   3 Find other Resources here (login credentials not needed)

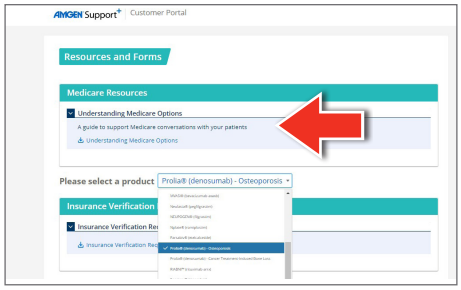


2. **After logging in, use the dashboard to access portal functions**, including initiating benefit verification services for patients, confirming missing information from requests or reviewing incomplete enrollment, and monitoring active patients (eg, verification status, next injections, treatment reminders).

   1 Initiate service for patients

   2 Review missing information or incomplete enrollment

   3 Monitor active patients



3. **From the dashboard, click "Resources" to access resources** for EVENITY® or Prolia®. This page can also be accessed through the homepage **without login credentials**.
   - Select EVENITY® or Prolia® from the drop-down menu to view resources by medication

CONTACT YOUR AMGEN REPRESENTATIVE WITH ANY QUESTIONS ABOUT THE Amgen SupportPlus CUSTOMER PORTAL

Please see EVENITY® Important Safety Information on page 17.
Please see Prolia® Important Safety Information on pages 17 and 18.

Step **1** of **5**

VERIFY BENEFITS, PRIOR AUTHORIZATION (PA) REQUIREMENTS, AND OUT-OF-POCKET COSTS

While coverage varies by payer, the benefits verification process is generally the same, regardless of which pathway your office chooses to obtain EVENITY® (romosozumab-aqqg) or Prolia® (denosumab).

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

- ❑ **Call your patient's health plan(s) or visit the health plan's website** to confirm the process for verifying benefits for EVENITY® or Prolia®. This process will vary depending on your patient's health plan(s)

  AMGEN® Support+ can assist your office in verifying your patient's benefits.
  Refer to **page 4** for more information

  - ❍ **Check with your patient's health plan** to see if the plan allows or mandates medications to be filled by a specialty pharmacy through the medical benefit. If the medication is filled this way, your office would only bill for administration
  - ❍ If your patient has Medicare and full Medicaid coverage, Medicare covers EVENITY® and Prolia® through Pharmacy Benefit (Part D)[1]

- ❑ **Collect information** that may be required by your patient's health plan:
  - ❍ **Copy of your patient's insurance cards** (primary, secondary, supplemental, tertiary, and pharmacy)
  - ❍ **Appropriate HCPCS code (J-Code) and ICD-10-CM diagnosis code(s)** (visit **CMS.gov** or refer to the Coding and Billing Guides for examples of codes. Download at **MyAmgenPortal.com/s/forms** or ask your Amgen representative for a copy)
  - ❍ **Documented prescription/medication order**

- ❑ **Review coverage** for EVENITY® or Prolia® with your patient:
  - ❍ Does the health plan have a **predetermination** process? **If yes**, follow the plan's process to determine coverage
  - ❍ Is a **PA** required? **If yes**, refer to the plan's documents or see the information to consider for **PA** requests on **page 16**
    - When completing a **PA** request, be sure to use the correct fulfillment pathway (medical or pharmacy benefit) prior authorization form. Document the **PA** approval in the medical record
    - To help support your clinical rationale for treatment, you can download a Sample Letter of Medical Necessity for EVENITY® or Prolia® at **MyAmgenPortal.com/s/forms** for assistance preparing your own letter
  - ❍ Is there a **step edit** requirement? **If yes**, ensure that you have documentation of the patient's previous therapies and reasons for discontinuation (eg, intolerance, failure, discontinuation of other osteoporosis therapies)
  - ❍ Does the health plan require a **specific site of care** (eg, hospital outpatient center, physician office)?
  - ❍ Is the patient responsible for any **out-of-pocket medication costs**? **If yes**, discuss patient's out-of-pocket costs with the patient before scheduling administration

    AMGEN® Support+ can help identify available financial resources.
    Refer to **page 4** for more information

Please see EVENITY® Important Safety Information on page 17.
Please see Prolia® Important Safety Information on pages 17 and 18.

Step **2** of **5**

ORDER EVENITY® (romosozumab-aqqg) OR PROLIA® (denosumab)

Proceed with Step 2 after collecting all information and obtaining answers to coverage questions in Step 1.

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

❑ **Schedule the patient for EVENITY® or Prolia® administration in your office**

- ❍ If a **PA** was required for EVENITY® or Prolia®, **confirm** that the **PA** was approved **before** scheduling the patient
- ❍ As a reminder, check with your patient's health plan to see if the plan allows or mandates medications to be filled by a specialty pharmacy through the medical benefit. If prescribing EVENITY® or Prolia® through a specialty pharmacy, see **page 12** for important items to discuss with your patients

❑ **Place an order** for EVENITY® or Prolia®. A list of preferred wholesalers and other wholesaler information is available on the Product Ordering Sheets. Download at **MyAmgenPortal.com/s/forms** or ask your Amgen representative for a copy

❑ **When it arrives, store EVENITY® or Prolia® in the refrigerator.**[2,3] Refer to Section 16 of the Prescribing Information for **EVENITY®** or **Prolia®** for complete storage and handling instructions

Step **3** of **5**

HEALTHCARE PROFESSIONAL ADMINISTERS EVENITY® OR PROLIA®

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

❑ **Collect the patient's co-pay** according to your billing practice at the time of visit

❑ **Healthcare professional administers EVENITY® or Prolia®**

- ❍ Refer to Section 2.3 of the Prescribing Information for **EVENITY®** or **Prolia®** for administration instructions

❑ After administration, **schedule the patient's next appointment** for EVENITY® or Prolia®

- **EVENITY® course of therapy:** 1 dose (2 injections) once monthly for 12 months[2]
- **Prolia® course of therapy:** 1 injection every 6 months[3]

Please see EVENITY® Important Safety Information on page 17.
Please see Prolia® Important Safety Information on pages 17 and 18.

Step **4** of **5**

BILL YOUR PATIENT'S INSURANCE

If your office uses a third-party biller, ensure that it bills all insurances (eg, primary, secondary, supplemental, and tertiary) for all services performed.

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

- ❑ **Confirm the payer's timeframe** for submitting claims after services are provided
- ❑ Be sure to bill all relevant insurance(s) (primary, secondary, supplemental, and tertiary) for **both administration and medication** as appropriate for each plan
  - ❍ If EVENITY® (romosozumab-aqqg) or Prolia® (denosumab) was **obtained through a specialty pharmacy** through the medical benefit, bill for **administration only**
- ❑ **Ensure you have the following information** on hand to submit your claim:
  - ❍ Medication and billing information (eg, HCPCS code, administration code, ICD-10-CM code[s])

HCPCS codes (J-Codes) and units:

- **EVENITY®**: J3111 (Injection, romosozumab-aqqg, 1 mg), 210 units[2,4]
- **Prolia®**: J0897 (Injection, denosumab, 1 mg), 60 units[3,4]

  - Visit **CMS.gov** or refer to Coding and Billing Guides. Download at **MyAmgenPortal.com/s/forms** or ask your Amgen representative for a copy

Determine appropriate administration code:

- 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.

  - ❍ Additional documentation, if applicable (eg, original diagnostic T-score and/or FRAX® predicted fracture risk); refer to the information to consider for **PA** requests on **page 16**
- ❑ **Document the PA number** when submitting the claim, if a **PA** is required

Step **5** of **5**

MANAGE REIMBURSEMENT

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

- ❑ Process payment claims for **both administration and medication**, if applicable
- ❑ **Be sure to review the remittance advice** to ensure appropriate payment once received
- ❑ If the claim is rejected or denied, **you may be able to appeal the decision**
  - ❍ Download a Sample Letter of Appeal at **MyAmgenPortal.com/s/forms** to help you prepare your own letter with the relevant information
- ❑ Contact your Amgen Access Specialist or Amgen SupportPlus for additional support with appeals

Please see EVENITY® Important Safety Information on page 17.
Please see Prolia® Important Safety Information on pages 17 and 18.

REFERRAL TO ALTERNATE SITES OF CARE

Step **1** of **3**

VERIFY BENEFITS, PRIOR AUTHORIZATION (PA) REQUIREMENTS, AND OUT-OF-POCKET COSTS

While coverage varies by payer, the benefits verification process is generally the same, regardless of which pathway your office chooses to obtain EVENITY® (romosozumab-aqqg) or Prolia® (denosumab).

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

- ❑ **Call your patient's health plan(s) or visit the health plan's website** to confirm the process for verifying benefits for EVENITY® or Prolia® and confirm if the plan(s) require a **specific site of care** (eg, hospital outpatient, physician office). This process will vary depending on your patient's health plan(s)

  AMGEN® Support+ can assist your office in verifying your patient's benefits. Refer to **page 4** for more information

  - ❍ Be sure to have the appropriate HCPCS code (J-Code) and ICD-10 codes on hand when calling

- ❑ **Collect information** that may be required by your patient's health plan:
  - ❍ **Copy of your patient's insurance cards** (primary, secondary, supplemental, tertiary, and pharmacy)
  - ❍ **Appropriate HCPCS code (J-Code) and ICD-10-CM diagnosis code(s)** (visit **CMS.gov** or refer to the Coding and Billing Guides for examples of codes. Download at **MyAmgenPortal.com/s/forms** or ask your Amgen representative for a copy)
  - ❍ **Documented prescription/medication order**

- ❑ **Review coverage** for EVENITY® or Prolia® with your patient:
  - ❍ Does the health plan have a **predetermination** process? **If yes**, follow the plan's process to determine coverage
  - ❍ Is a **PA** required? **If yes**, refer to the plan's documents or see the information to consider for **PA** requests on **page 16**
    - When completing a **PA** request, be sure to use the correct fulfillment pathway (medical or pharmacy benefit) prior authorization form. Document the **PA** approval in the medical record
    - To help support your clinical rationale for treatment, you can download a Sample Letter of Medical Necessity for EVENITY® or Prolia® at **MyAmgenPortal.com/s/forms** for assistance preparing your own letter
  - ❍ Is there a **step edit** requirement? **If yes**, ensure that you have documentation of the patients' previous therapies and reasons for discontinuation (eg, intolerance, failure, discontinuation of other osteoporosis therapies)
  - ❍ Does the health plan require a **specific site of care** (eg, hospital outpatient center, physician office)?
  - ❍ Is the patient responsible for any **out-of-pocket medication costs**? **If yes**, discuss patient's out-of-pocket costs with the patient before scheduling administration

    AMGEN® Support+ can help identify available financial resources. Refer to **page 4** for more information

Please see EVENITY® Important Safety Information on page 17.
Please see Prolia® Important Safety Information on pages 17 and 18.

REFERRAL TO ALTERNATE SITES OF CARE

Step **2** of **3**

LOCATE AN ALTERNATE SITE OF CARE

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

- ❑ **If you do not already have an established alternate site of care, visit EVENITYFinder.com or ProliaFinder.com** to locate an alternate site of care for the applicable product*
  - ❍ Enter your patient's preferred treatment location (eg, City, State, and/or ZIP Code)
  - ❍ For Prolia® (denosumab), select "Treatment Site" from the drop-down menu. If your office is sending the prescription to a pharmacy, skip to **page 12**
  - ❍ Click "Find Locations"
- ❑ **Call the alternate site of care** to confirm the process for referring patients to their site for administration. Determine who will be responsible for verifying benefits. If it is your office, see Step 1 on the previous page

*Note that these websites are not an endorsement of the pharmacies or treatment sites listed and are not comprehensive lists of all pharmacies or treatment sites that handle EVENITY® or Prolia® in your area. See additional details on those websites.

Step **3** of **3**

ESTABLISH COMMUNICATION WITH THE ALTERNATE SITE OF CARE

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

- ❑ Once a treatment site is located, **call the site directly to confirm** the following:
  - ❍ The site can administer EVENITY® (romosozumab-aqqg) or Prolia® for the patient
  - ❍ The appropriate process used to refer patients (optional Treatment Referral Form is located on **EVENITYFinder.com** or **ProliaFinder.com**)
  - ❍ Who will submit the **PA** request (if needed)
  - ❍ How your office will be notified when the patient receives EVENITY® or Prolia® and who will schedule the next administration
    - **EVENITY® course of therapy**: 1 dose (2 injections) once monthly for 12 months[2]
    - **Prolia® course of therapy**: 1 injection every 6 months[3]
- ❑ **Use the preferred referral process** from alternate site of care
- ❑ **Be sure to collect all required information:**
  - ❍ Treatment site information (eg, physician and site name, site address, contact person)
  - ❍ Patient demographic and insurance information (primary, secondary, supplemental, tertiary, and pharmacy)
  - ❍ Patient medical information (eg, diagnosis code, original diagnostic T-score, prior therapies and reasons for discontinuation)
  - ❍ Referring physician information and signature, and provider order of EVENITY® or Prolia® documented in the chart
- ❑ **Send the required information** to the alternate site of care

THE ALTERNATE SITE OF CARE WILL **BILL YOUR PATIENT'S HEALTH PLAN FOR BOTH ADMINISTRATION AND PRODUCT**

Please see EVENITY® Important Safety Information on page 17.
Please see Prolia® Important Safety Information on pages 17 and 18.

PHARMACY/SPECIALTY PHARMACY
(USING THE PHARMACY BENEFIT FOR PROLIA® (DENOSUMAB))

Step **1** of **5**

VERIFY BENEFITS, PRIOR AUTHORIZATION (PA) REQUIREMENTS, AND OUT-OF-POCKET COSTS

While coverage varies by payer, the benefits verification process is generally the same, regardless of which pathway your office chooses to obtain medication.

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

- ❑ **Call your patient's health plan(s) or visit the health plan's website** to confirm the process for verifying benefits for Prolia®. This process will vary depending on your patient's health plan(s)

  AMGEN® Support+ can assist your office in verifying your patient's benefits.
  Refer to **page 4** for more information

  - ❍ **Check with your patient's health plan** to see if the plan allows or mandates medications to be filled by a specialty pharmacy through the medical benefit. If the medication is filled this way, your office would only bill for administration

- ❑ **Collect information** that may be required by your patient's health plan:
  - ❍ **Copy of your patient's insurance cards** (primary, secondary, supplemental, tertiary, and pharmacy)
  - ❍ **Appropriate HCPCS code (J-Code) and ICD-10-CM diagnosis code(s)** (visit **CMS.gov** or refer to the Prolia® Coding and Billing Guide for examples of codes. Download at **MyAmgenPortal.com/s/forms** or ask your Amgen representative for a copy)
  - ❍ **Documented prescription/medication order**

- ❑ **Review coverage** for Prolia® with your patient:
  - ❍ Does the health plan have a **predetermination** process? **If yes**, follow the plan's process to determine coverage
  - ❍ Is a **PA** required? **If yes**, refer to the plan's documents or see the information to consider for **PA** requests on **page 16**
    - When completing a **PA** request, be sure to use the correct fulfillment pathway (medical or pharmacy benefit) prior authorization form. Document the **PA** approval in the medical record
    - To help support your clinical rationale for treatment, you can download a Sample Letter of Medical Necessity for Prolia® at **MyAmgenPortal.com/s/forms** for assistance preparing your own letter
  - ❍ Is there a **step edit** requirement? **If yes**, ensure that you have documentation of the patient's previous therapies and reasons for discontinuation (eg, intolerance, failure, discontinuation of other osteoporosis therapies)
  - ❍ Does the health plan require a **specific site of care** (eg, hospital outpatient center, physician office)?
  - ❍ Is the patient responsible for any **out-of-pocket medication costs**? **If yes**, discuss patient's out-of-pocket costs with the patient before scheduling administration

    AMGEN® Support+ can help identify available financial resources.
    Refer to **page 4** for more information

Please see Prolia® Important Safety Information on pages 17 and 18.

PHARMACY/SPECIALTY PHARMACY
(USING THE PHARMACY BENEFIT FOR PROLIA® (DENOSUMAB))

Step **2** of **5**

SEND THE PRESCRIPTION FOR PROLIA® TO THE PHARMACY/SPECIALTY PHARMACY

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

- ❑ **Select pharmacy (could be mandated), or visit ProliaFinder.com** for help finding a pharmacy in your area. Use the instructions below if your office chooses to use **ProliaFinder.com** to locate a pharmacy*
  - ❍ Enter your patient's preferred treatment location (eg, City, State, and/or ZIP Code)
  - ❍ Select "Pharmacy Site" from the drop-down menu
  - ❍ Click "Find Locations"
- ❑ **Contact your patient** to discuss
  - ❍ Enrolling in the Amgen SupportPlus Co-Pay Program (for eligible commercially insured patients)
  - ❍ Answering the call from the pharmacy to collect payment, which may come from an unknown toll-free number
  - ❍ Having credit card or co-pay card information on hand to pay any out-of-pocket costs owed to the pharmacy
  - ❍ Ensuring the pharmacy ships medication to your office for administration
  - ❍ Scheduling the patient for administration in your office
- ❑ **When received, store Prolia® in the refrigerator.**[3] Refer to Section 16 of the Prescribing Information for **Prolia®** for complete storage and handling instructions

*Note that this website is not an endorsement of the pharmacies listed and is not a comprehensive list of all pharmacies that handle Prolia® in your area. See additional details on the website.

Step **3** of **5**

HEALTHCARE PROFESSIONAL ADMINISTERS MEDICATION

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

- ❑ **Collect the patient's co-payment** for administration only according to your billing practice at the time of visit
- ❑ **Healthcare professional administers Prolia®**
  - ❍ Refer to Section 2.3 of the Prescribing Information for **Prolia®** for administration instructions
- ❑ After administration, **schedule the patient's next appointment** for Prolia®
  - **– Prolia® course of therapy:** 1 injection every 6 months[3]

Please see Prolia® Important Safety Information on pages 17 and 18.

PHARMACY/SPECIALTY PHARMACY
(USING THE PHARMACY BENEFIT FOR PROLIA® (DENOSUMAB))

Step **4** of **5**

BILL YOUR PATIENT'S INSURANCE

If your office uses a third-party biller, ensure that it bills all insurances (eg, primary, secondary, supplemental, and tertiary) for all services performed.

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

- ❑ **Confirm the payer's timeframe** for submitting claims after services are provided
- ❑ Be sure to bill all relevant insurance(s) (primary, secondary, supplemental, and tertiary) for **administration only** as appropriate for each plan
- ❑ **Ensure you have the following information** on hand to submit your claim:
  - ❍ Medication and billing information (eg, HCPCS code, administration code, ICD-10-CM code[s])

HCPCS code (J-Code) and units:
- **Prolia®**: J0897 (Injection, denosumab, 1 mg), 60 units[3,4]
- Visit **CMS.gov** or refer to the Prolia® Coding and Billing Guide. Download at **MyAmgenPortal.com/s/forms** or ask your Amgen representative for a copy

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Determine appropriate administration code:
- 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.

  - ❍ Additional documentation, if applicable (eg, original diagnostic T-score and/or FRAX® predicted fracture risk); refer to the information to consider for **PA** requests on **page 16**

- ❑ **Document the PA number** when submitting the claim, if a **PA** is required

Step **5** of **5**

MANAGE REIMBURSEMENT

WHO IS RESPONSIBLE FOR THIS STEP?

Name _____

- ❑ Process payment claims for **administration only**
- ❑ **Be sure to review the remittance advice** to ensure appropriate payment once received
  - ❍ Download a Sample Letter of Appeal at **MyAmgenPortal.com/s/forms** to help you prepare your own letter with the relevant information
- ❑ Contact your Amgen Access Specialist or Amgen SupportPlus for additional support with appeals

Please see Prolia® Important Safety Information on pages 17 and 18.

RESOURCES FOR EACH STEP

For resources on the Amgen® SupportPlus Customer Portal, visit MyAmgenPortal.com/s/forms, and select EVENITY® (romosozumab-aqqg) or Prolia® (denosumab) from the drop-down menu to view resources for each product. You do not need login credentials to access these resources.

FULFILLMENT PATHWAYS BY INSURANCE TYPE

	Medical Benefit Pathway			Pharmacy Benefit Pathway
Health Plans	**Buy and Bill/ Physician Purchase**	**Referral***	**Specialty Pharmacy**	**Specialty/Retail Pharmacy**
Medicare Part B	✓	✓	✗	✗
Medicare Part D	✗	✗	✗	✓
Medicare Advantage†	✓	✓	✓	✓
Commercial†	✓	✓	✓	✓

*Referral to alternate site of care.

†Health plan may mandate which pathway to fulfill EVENITY® or Prolia®.

VERIFY BENEFITS, PA REQUIREMENTS, AND OUT-OF-POCKET COSTS

Insurance Verification Forms, Coding and Billing Guides, Sample Letters of Medical Necessity
Download at MyAmgenPortal.com/s/forms

Amgen SupportPlus Customer Portal
Register at MyAmgenPortal.com

Amgen SupportPlus Customer Portal Quick Reference Guide
Download at MyAmgenPortal.com

Amgen SupportPlus Co-pay program
Visit: AmgenSupportPlus.com/copay*
Phone: 1-866-264-2778

*Eligibility criteria and program maximums apply. See www.amgensupportplus.com/copay for full Terms and Conditions.

For more information on financial resources for your patients, see **page 4**.

ORDER EVENITY® OR PROLIA®

Preferred Distributor Lists
Access at MyAmgenPortal.com/s/forms

EVENITY® Product Ordering Sheet
Download at MyAmgenPortal.com/s/forms

Prolia® Product Ordering Sheet
Download at MyAmgenPortal.com/s/forms

Please see EVENITY® Important Safety Information on page 17.
Please see Prolia® Important Safety Information on pages 17 and 18.

LOCATE AN ALTERNATE SITE OF CARE

Finder Sites
EVENITYFinder.com or ProliaFinder.com
Treatment Referral Forms
Download at EVENITYFinder.com or ProliaFinder.com

SEND THE PRESCRIPTION FOR PROLIA® (denosumab) TO THE PHARMACY

Prolia® Preferred Specialty Pharmacies
Access at ProliaHCP.com/support-and-access/medicare-part-d#
Prolia Finder™
ProliaFinder.com

BILL YOUR PATIENT'S INSURANCE

Coding and Billing Guides
Download at MyAmgenPortal.com/s/forms

Codes and information to consider for claims submission

	EVENITY® (romosozumab-aqqg)	Prolia® (denosumab)
HCPCS code (J-Code)[4]	J3111 (Injection, romosozumab-aqqg, 1 mg)	J0897 (Injection, denosumab, 1 mg)
Number of units	210 units (for one kit)[2,*]	60 units[3]
Administration code	Appropriate administration code to be determined by the provider	

*Each EVENITY® kit contains one dose, which is 2 injections for a total dose of 210 mg.[2]

Determine appropriate administration code
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.

MANAGE REIMBURSEMENT

Sample Letters of Appeal
Download at MyAmgenPortal.com/s/forms

BONE MATTERS®

RESOURCE FOR PATIENTS

Help your patients enroll in Bone Matters®, a comprehensive support program to keep them informed, inspired, and on track throughout treatment

Visit **EVENITY.com/signup** or **Prolia.com/bonematters** to get your patients started

Please see EVENITY® Important Safety Information on page 17.
Please see Prolia® Important Safety Information on pages 17 and 18.

INFORMATION TO CONSIDER FOR PRIOR AUTHORIZATION (PA) REQUESTS

The information below represents examples of criteria that health plans may ask your office to provide when requesting a PA for EVENITY® (romosozumab-aqqg) or Prolia® (denosumab). Consult the health plan's policy for specific PA criteria and documentation requirements.

Appropriate HCPCS code (J-Code) and ICD-10-CM diagnosis code(s)

Visit **CMS.gov** or download the full **Coding and Billing Guides** at **MyAmgenPortal.com/s/forms** for example codes

Determine appropriate administration code:

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.

Some examples of prior osteoporosis therapies include:

FOSAMAX® (alendronate sodium)[5] | RECLAST® (zoledronic acid)[6] | TYMLOS® (abaloparatide)[7] | FORTEO® (teriparatide)[7]

Risk factors for fracture

Examples of risk factors:[7]

- Prior fragility fracture
- Low BMD (≤ -2.5)
- Age ≥65 years
- Low body weight
- Long-term glucocorticoid use
- Excessive alcohol intake (>3 drinks/day)
- Cigarette smoking
- Immobilization
- Parental history of hip fracture
- Risk of falling
- Rheumatoid arthritis
- Diabetes

Other considerations (include test results and date as appropriate)

- Original diagnostic T-score[7]
- Is the patient taking supplemental calcium and vitamin D?[6]
- Fracture risk assessment (FRAX® or Trabecular Bone Score)[7]
- Impaired kidney function[7]
  - Estimated glomerular filtration rate (eGFR) results
- Patients experiencing bone loss while on drugs that may cause skeletal harm[8]
- Has the patient experienced a loss of height?[7]
- Does the patient have a gastrointestinal disorder (eg, gastroesophageal reflux disease)?[9]
- Is the patient at very high risk for fracture?[7]
  - Had recent fracture (within past 12 months)
  - Had fracture while on approved therapy for osteoporosis
  - Had fractures while on drugs that may cause skeletal harm
  - Experienced multiple fractures
  - Very low T-score (eg, less than -3.0)
  - High risk for falls or history of injurious falls

EVENITY® Prior Authorization Tip Sheet: Download at MyAmgenPortal.com/s/forms

Prolia® Prior Authorization Tip Sheet: Download at MyAmgenPortal.com/s/forms

Please see EVENITY® Important Safety Information on page 17.

Please see Prolia® Important Safety Information on pages 17 and 18.

EVENITY® (romosozumab-aqqg) 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 EVENITY® full Prescribing Information, including Medication Guide.

PROLIA® (denosumab) IMPORTANT SAFETY INFORMATION

SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE:

Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following Prolia administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiating Prolia in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with Prolia in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Contraindications: Prolia® is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating Prolia®. Prolia® is contraindicated in women who are pregnant and may cause fetal harm. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment with Prolia®. Prolia® is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling and urticaria.

Severe Hypocalcemia and Mineral Metabolism Changes: Prolia can cause severe hypocalcemia and fatal cases have been reported. Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia. Adequately supplement all patients with calcium and vitamin D.

PROLIA® (denosumab)

IMPORTANT SAFETY INFORMATION (cont'd)

In patients without advanced chronic kidney disease who are predisposed to hypocalcemia and disturbances of mineral metabolism (e.g. treatment with other calcium-lowering drugs), assess serum calcium and mineral levels (phosphorus and magnesium) 10 to 14 days after Prolia injection.

Same Active Ingredient: Prolia® contains the same active ingredient (denosumab) found in XGEVA®. Patients receiving Prolia® should not receive XGEVA®.

Hypersensitivity: Clinically significant hypersensitivity including anaphylaxis has been reported with Prolia®. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of Prolia®.

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 Prolia®. An oral exam should be performed by the prescriber prior to initiation of Prolia®. A dental examination with appropriate preventive dentistry is recommended prior to treatment in patients with risk factors for ONJ such as invasive dental procedures, diagnosis of cancer, concomitant therapies (e.g. chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and co-morbid disorders. Good oral hygiene practices should be maintained during treatment with Prolia®. The risk of ONJ may increase with duration of exposure to Prolia®.

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. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of Prolia® should be considered based on individual benefit-risk assessment.

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

During Prolia® 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 Prolia® therapy should be considered, pending a risk/benefit assessment, on an individual basis.

Multiple Vertebral Fractures (MVF) Following Discontinuation of Prolia® Treatment: Following discontinuation of Prolia® treatment, fracture risk increases, including the risk of multiple vertebral fractures. New vertebral fractures occurred as early as 7 months (on average 19 months) after the last dose of Prolia®. Prior vertebral fracture was a predictor of multiple vertebral fractures after Prolia® discontinuation. Evaluate an individual's benefit/risk before initiating treatment with Prolia®. If Prolia® treatment is discontinued, patients should be transitioned to an alternative antiresorptive therapy.

Serious Infections: In a clinical trial (N = 7808), serious infections leading to hospitalization were reported more frequently in the Prolia® group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear, were more frequent in patients treated with Prolia®.

Endocarditis was also reported more frequently in Prolia®-treated patients. The incidence of opportunistic infections and the overall incidence of infections were similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis.

Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Prolia®, prescribers should assess the need for continued Prolia® therapy.

Dermatologic Adverse Reactions: Epidermal and dermal adverse events such as dermatitis, eczema and rashes occurred at a significantly higher rate with Prolia® compared to placebo. Most of these events were not specific to the injection site. Consider discontinuing Prolia® if severe symptoms develop.

Musculoskeletal Pain: Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking Prolia®. Consider discontinuing use if severe symptoms develop.

Suppression of Bone Turnover: Prolia® resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment are unknown. Monitor patients for consequences, including ONJ, atypical fractures, and delayed fracture healing.

Adverse Reactions: The most common adverse reactions (>5% and more common than placebo) are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis. Pancreatitis has been reported with Prolia®.

The overall incidence of new malignancies was 4.3% in the placebo group and 4.8% in the Prolia® group. A causal relationship to drug exposure has not been established. Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

Please see Prolia® full Prescribing Information, including Medication Guide.

GLOSSARY OF KEY TERMS

Alternate site of care: A treatment site, such as an infusion center, where medication can be administered to patients

Appeal: A process in which a healthcare provider or patient can request that the health plan review a decision to deny a physician-ordered service[10]

Benefits: Healthcare items or services covered under a patient's health insurance plan[11]

Benefits verification: A review of medical or pharmacy benefits through the patient's insurance, including the coverage and cost to the patient[12]

Buy and bill: A process in which a healthcare provider purchases medication for in-office administration

Claim: A request for payment submitted to the health plan for items or services that may be covered by the plan[10]

Co-insurance: An amount the patient may be required to pay as their share of the cost for services after they pay any deductibles. Co-insurance is usually a percentage (eg, 20%)[1]

Co-pay (or co-payment): A fixed amount paid by the patient for a covered healthcare service[10]

Denial: Refusal by the health plan to approve or pay for a medical claim (eg, tests or procedures ordered by the healthcare provider)[13]

Diagnosis code (ICD-10): A code used for billing describing the patient's illness[11]

HCPCS code (J-Code): Standardized code representing medical procedures, supplies, products, and services used to facilitate processing health insurance claims by Medicare and other insurers[14]

Predetermination: A request submitted by a provider to verify benefits and ensure a service aligns with the plan's medical policy before it's provided[15]

Prior authorization (PA): A tool used by health plans requiring prescribers to receive pre-approval for certain drugs in order for the drugs to be covered for appropriate patients[16]

Reimbursement: Money compensation from the health plan for medical services provided by the healthcare provider[11]

Remittance advice: Document attached to a processed claim explaining the information regarding coverage and payment on a claim[11]

Retail pharmacy: An independent pharmacy or chain pharmacy dispensing medications to the general public[16]

Specialty pharmacy: A type of pharmacy that focuses on high-cost, high-touch medications for patients with complex disease states[17]

Step edit (or step therapy): The practice of initiating drug therapy with the most cost-effective and safest drug, and "stepping up" to alternative agents only when the initial therapy fails[16]

Summary of benefits: A document that summarizes the patient's deductible, out-of-pocket responsibility, and coverage details (eg, if a PA is required)

BMD=Bone Mineral Density; HCPCS=Healthcare Common Procedure Coding System; ICD-10=International Classification of Diseases, 10th Revision.

Please see EVENITY® (romosozumab-aqqg) Important Safety Information page 17.

Please see Prolia® (denosumab) Important Safety Information on pages 17 and 18.

CONTACT INFORMATION

Product information	**EVENITY® (romosozumab-aqqg)** Provider Website: **EVENITYProliaHCP.com** Patient Website: **EVENITY.com** **Prolia® (denosumab)** Provider Website: **ProliaHCP.com** Patient Website: **Prolia.com**
Hub Service	**Amgen SupportPlus** **Phone:** 1-866-264-2778 **Fax:** 1-877-877-6542 **Hours of operation:** Monday through Friday, 9:00 am to 8:00 pm ET
Customer Portal	**Amgen SupportPlus Customer Portal** **Website: MyAmgenPortal.com**
Finder Sites	**EVENITY®: EVENITYFinder.com** **Prolia®: ProliaFinder.com**
Co-pay Program	**Amgen SupportPlus Co-Pay Program:** **www.amgensupportplus.com/copay** **Phone:** 1-866-264-2778 (Monday through Friday, 9:00 am to 8:00 pm ET)

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