BUY AND BILL

5-step guide

FOR OFFICE STAFF

Indications

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.

Prolia® is indicated for treatment to increase bone mass in men 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.

Prolia® is indicated for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Prolia® is indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia® also reduced the incidence of vertebral fractures.

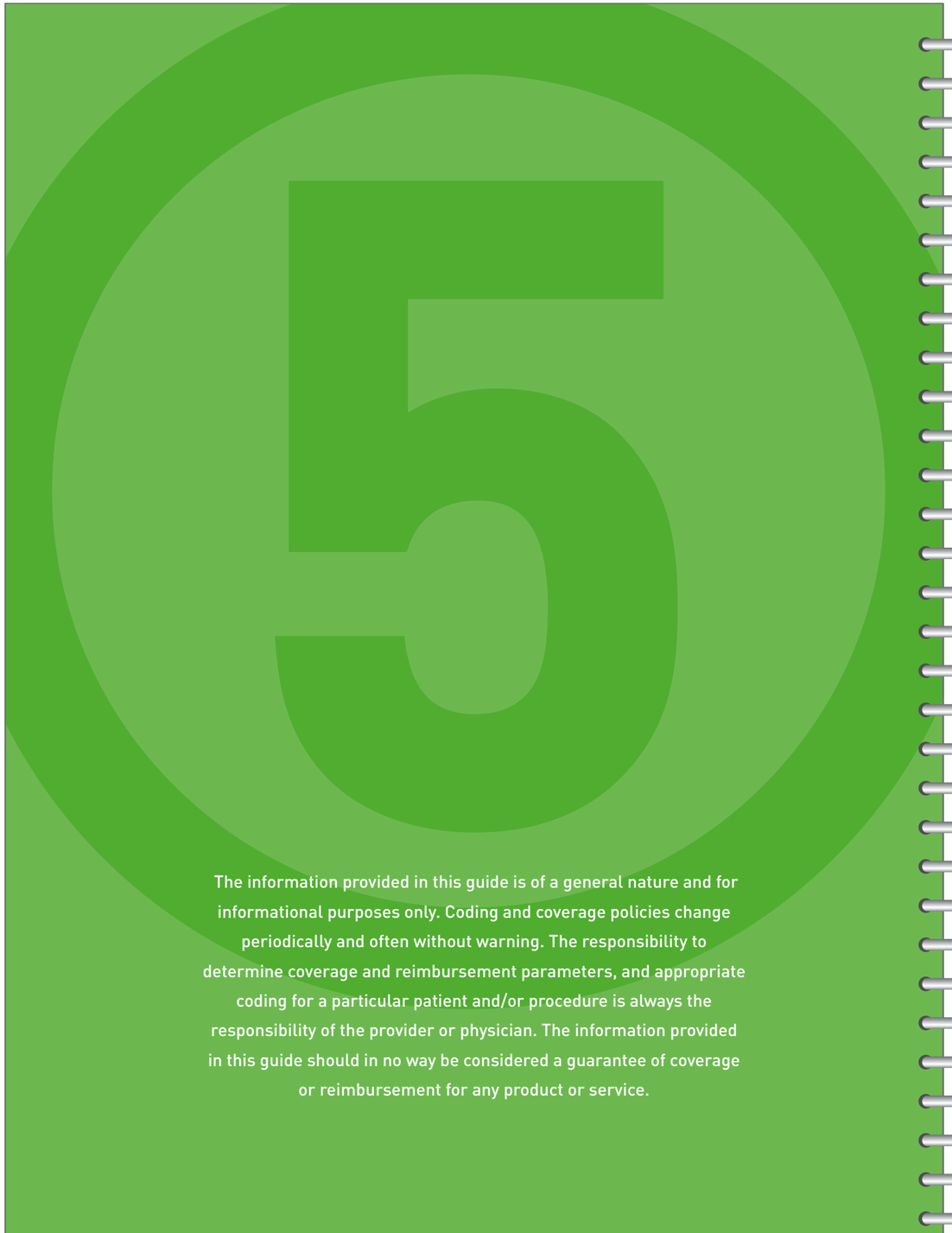
Prolia® is indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Important Safety Information

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.

Please see additional Important Safety Information on pages 16-17, and click here for the Prolia® full Prescribing Information, including Medication Guide.

prolia® (denosumab) injection



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.

Once the physicians in your office prescribe Prolia® for clinically appropriate patients, there are two ways to fulfill their prescription.

- Buy and bill pathway
- Pharmacy pathway

This guide focuses on the buy and bill pathway.

The buy and bill pathway may lower out-of-pocket costs for some of your patients[1]; however, it is important to follow the process correctly for each health plan.

Using this guide

This guide was designed to help you navigate the 5 steps of the buy and bill process for Prolia® patients, from first assessment of coverage to final receipt of reimbursement. The numbers match each step, with suggestions, best practices, and frequently asked questions for each section. Whether you're new to buy and bill, or just want to make sure you are completing all the steps correctly, keep this guide handy to refer to whenever questions come up.

For additional information, please contact your Prolia® Field Reimbursement Specialist for more support.

Please see Important Safety Information on pages 16-17.

prolia® (denosumab) injection

ASSESS COVERAGE

Verify benefits for your Prolia® (denosumab) patient

- Verify benefits with the payer
- You may also verify benefits by submitting the Insurance Verification Form to Amgen Assist® via fax or the Amgen Assist® Support Portal
  - Fax: 1-877-877-6542
  - Portal registration: www.AmgenAssistSupport.com
- Receive a Summary of Benefits within approximately 5 business days
  - The Summary of Benefits will indicate if prior authorization is required, as well as the patient's co-pay amount or money owed
- Call the patient regarding their financial responsibility

CONFIRM THAT

- The plan covers Prolia® without prior authorization or step edit (in network)
- The timing of submission meets specific payer policy requirements

SCHEDULE YOUR PATIENT

- New patient: As needed
- Returning patient: In accordance with the Prolia® prescribing information, Prolia® is administered as one shot every 6 months

THE **AMGEN ASSIST®** SUPPORT PORTAL MAY HELP WITH:

- Completing and submitting Insurance Verification Forms
- Receiving the Summary of Benefits—with instant verification where available

Ask your Prolia® Field Reimbursement Specialist or your sales representative for a demonstration today

prolia® (denosumab) injection

1 Assess Coverage
2 Order Prolia® (denosumab)
3 Administer Prolia® (denosumab)
4 Bill Insurance
5 Manage Reimbursement

Please see Important Safety Information on pages 16-17.

ASSESS COVERAGE

Consider These Best Practices

- Appropriately documenting information in the medical record can help the claims process run smoothly. The information should be complete and accurate. Claims document may include:[2-4]
  - Diagnosis information
  - Original diagnosis fracture notes
  - All medications the patient is taking
  - Other considerations associated with risk for fracture
  - For prior authorizations, capture any treatments to which the patient did not respond or did not tolerate
- Use a prepopulated Insurance Verification Form with the prescribing physician's information and keep a copy on file
- Send a copy of the patient's insurance card with the Insurance Verification Form to Amgen Assist®. Verify that the card is current and coverage hasn't changed; recheck coverage at every visit
- Identify and select the most efficient way to communicate with payers
- Wait until benefits are confirmed before scheduling an injection
- Your Prolia® (denosumab) Field Reimbursement Specialist has a range of support resources to help you throughout the process, such as:
  - Sample Insurance Verification Form
  - Sample Prior Authorization Form
  - Sample Claim Form
  - Coding and Billing Guide
  - Billing and Coding Reference Sheets

FAQ

My patient's plan has a prior authorization requirement for Prolia®. What kind of information may be required for a prior authorization?

Each prior authorization requirement may be different, so you will need to review the specific plan's requirements to make sure you are providing the correct information. Examples of required information may include:[5,6]

- Prior osteoporosis therapy, intolerance/failure of previous treatments, and reason for discontinuation
- Diagnosis code
- Original T-score used for diagnosis
- Lab results[7]

To help with the prior authorization process, consider documenting this information thoroughly and accurately with all patients.

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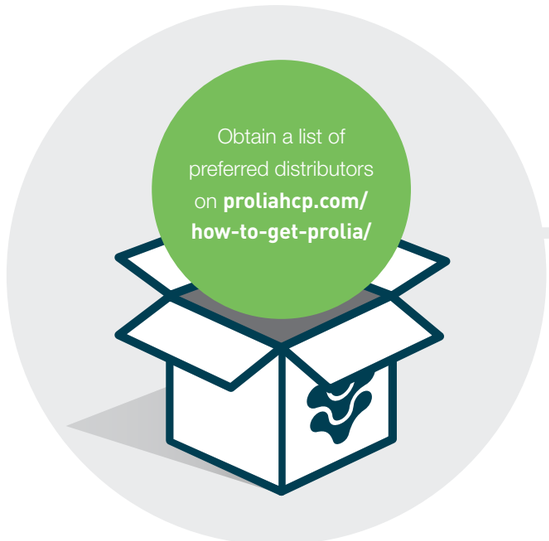
ORDER PROLIA® (DENOSUMAB)

If you're new to buy and bill, you will need to set up a wholesaler account. For a list of preferred distributors, visit: **proliahcp.com/how-to-get-prolia/**

Consider These Best Practices

As a reminder, Prolia® should be stored in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton. Do not freeze. See the full Prescribing Information for complete storage and handling instructions.



FAQ

How soon will Prolia® arrive in the office after it is ordered?

Most orders arrive in 2-3 business days.* For a more accurate estimation, confirm expected timing for your office with your wholesaler.

*Shipping and estimated arrival times are dependent on the wholesaler. Please refer to their policies and procedures for a timing schedule, if needed.

1. Assess Coverage
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prolia® (denosumab) injection

Please see Important Safety Information on pages 16-17.

ADMINISTER PROLIA® (DENOSUMAB)

Patient coverage should be confirmed before the patient receives the injection. Then:

COLLECT

Collect patient co-pay according to your billing practice

INJECT

Prescribing physician or appropriate medical staff member administers a Prolia® **injection** per Prescribing Information[8]

SCHEDULE

Plan and **schedule** the patient's next injection every **6 months** (per the prescribing information)[8]

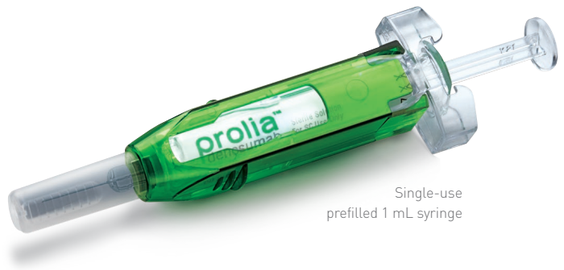
Consider These Best Practices

- Establish a consistent office policy for collecting payment from patients
- Encourage office staff working on patient materials to use coding reference cards and/or superbills to ensure proper documentation of patient encounters
- Ask your Prolia® Field Reimbursement Specialist to schedule in-service training for medical staff administering Prolia®
- Use Amgen Assist® to confirm coverage and receive a Summary of Benefits to keep with patient records

FAQ

When should the next injection be scheduled and administered?

Per the Prolia® prescribing information, Prolia® is administered as one shot every 6 months.[8] Review the payer policy on acceptable timing of claim submission.



Single-use prefilled 1 mL syringe

60 mg subcutaneous injection administered in the upper arm, upper thigh, or abdomen by a healthcare professional.[8]

- Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia®
- Adequately supplement all patients with calcium and vitamin D
- Pregnancy must be ruled out prior to administration of Prolia®
- Multiple vertebral fractures have been reported following Prolia® discontinuation

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prolia® (denosumab) injection

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BILL INSURANCE

Use the Prolia® (denosumab) Coding and Billing Guide as a helpful resource when you submit claims

- You can access the guide at www.proliahcp.com under How to Get Prolia® and by clicking the Coding and Billing link or by contacting Amgen Assist®
- Consider using an electronic submission process to improve payment turnaround time and reduce errors

CODES THAT MAY BE USED FOR PROLIA®

- **Prolia® coding information**[9]
  J-Code: J0897 (injection, denosumab, 1 mg)*
- **Administration and professional service coding information**[10,†]
  CPT code: 96372
- **Diagnosis code information (ICD-10-CM)**[11]
  Without current osteoporotic fracture:
  – M81.0 (Age-related osteoporosis without current pathological fracture)[12,‡]
  – M81.8 (Other osteoporosis without current pathological fracture)[12,‡]
  With current osteoporotic fracture:[12,§]
  – M80.0 (Age-related osteoporosis with current pathological fracture)
  – M80.8 (Other osteoporosis with current pathological fracture)

Diagnosis code examples 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. These codes are not intended to be used for non-FDA approved uses. The information provided is not a guarantee of coverage or payment (partial or full). Actual benefits are determined by each plan administrator in accordance with its respective policy and procedures.

*Use of a 60 mg prefilled syringe of Prolia® is reported as 60 units.

†This code may be available to report administration of Prolia®. 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.

‡According to the ICD-10-CM Official Guidelines for Coding and Reporting, M81 code is for use for 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.[12]

§ICD-10-CM codes for patients with current osteoporotic fracture are determined by anatomic site, laterality, and encounter type.[12]

Please see Important Safety Information on pages 16-17.

Consider These Best Practices

- Regularly check records to make sure coding is correct; regularly review and update coding sheets[13]
- Learn coding and billing requirements on a payer-specific basis[2]
- Maintain copies of all submitted claims
- Respond promptly to documentation requests from the payer

FAQs

How soon after service do I need to submit a claim?

24 to 48 hours is the typical time between service being provided and being billed.[14,15,*]

Is there a way to check on the status of a claim?

Call Amgen Assist® for information about the status of a claim. If you're not currently using Amgen Assist®, contact your payer directly to check the status of your claim.

*Based on data from two health plans.

prolia® (denosumab) injection

MANAGE REIMBURSEMENT

Considerations for claims payment and collections[16-18]

- Payers are adopting electronic methods for sending payments to providers
- Once payment has been received, it is important to review the remittance advice to ensure appropriate payment
- If the claim has been rejected or denied, an appeal may be possible

Consider These Best Practices[13]

- Establish policy and process for collecting payment from patients
- Establish process for routinely following up on delinquent claims

FAQ

What if my claim is denied?

This should not happen often[19] because there are well-established payer policies for Prolia®. In the case that it does, contact your Prolia® Field Reimbursement Specialist or Amgen Assist® for help with appealing denied on-label claims for Prolia®. They can help your practice with the appeal process and follow up until a decision is reached.

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Important Safety Information

- **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.
- **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®.
- **Hypocalcemia:** Hypocalcemia may worsen with the use of Prolia®, especially in patients with severe renal impairment. In patients predisposed to hypocalcemia and disturbances of mineral metabolism, including treatment with other calcium-lowering drugs, clinical monitoring of calcium and mineral levels is highly recommended within 14 days of Prolia® injection. Concomitant use of calcimimetic drugs may worsen hypocalcemia risk and serum calcium should be closely monitored. Adequately supplement all patients with calcium and vitamin D.
- **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) in women with postmenopausal osteoporosis, 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:** In the same clinical trial in women with postmenopausal osteoporosis, 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:** In clinical trials in women with postmenopausal osteoporosis, 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 these consequences, including ONJ, atypical fractures, and delayed fracture healing.
- **Adverse Reactions:** The most common adverse reactions (> 5% and more common than placebo) in women with postmenopausal osteoporosis are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis. The most common adverse reactions (> 5% and more common than placebo) in men with osteoporosis are back pain, arthralgia, and nasopharyngitis. Pancreatitis has been reported with Prolia®.

  In women with postmenopausal osteoporosis, the overall incidence of new malignancies was 4.3% in the placebo group and 4.8% in the Prolia® group. In men with osteoporosis, new malignancies were reported in no patients in the placebo group and 4 (3.3%) patients in the Prolia® group. A causal relationship to drug exposure has not been established.

  The most common adverse reactions (> 3% and more common than active-control group) in patients with glucocorticoid-induced osteoporosis are back pain, hypertension, bronchitis, and headache.

  The most common (per patient incidence ≥ 10%) adverse reactions reported with Prolia® in patients with bone loss receiving ADT for prostate cancer or adjuvant AI therapy for breast cancer are arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials. Additionally, in Prolia®-treated men with nonmetastatic prostate cancer receiving ADT, a greater incidence of cataracts was observed.

  Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

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

REFERENCES: 1. Data on file, Amgen. 2018. **2.** Green MA. *Understanding Health Insurance: A Guide to Billing and Reimbursement.* Thirteenth Edition. 2017. Cengage Learning, Boston, MA. **3.** Centers for Medicare & Medicaid Services. National Government Services. Future Local Coverage Article: Denosumab (Prolia, Xgeva) - Related to LCD L33394 (A52399). https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52399&v. Accessed February 18, 2019. **4.** Novitas. Medical Review – Active Edits and Probes. Jurisdiction L. 2017. http://www.novitas-solutions.com/cs/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=00007720&prot%E2%80%A6. Accessed January 24, 2019. **5.** Affinity PA Form 2017. www.affinityplan.org. Accessed February 15, 2019. **6.** Meridian PA Form 2017. https://corp.mhplan.com/en/prior-authorization. Accessed February 15, 2019. **7.** Cosman F, de Beur SJ, LeBoff MS, Lewiecki EM, Tanner B, Randall S, Lindsay R. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2014;25(10):2359-2381. **8.** Prolia® (denosumab) prescribing information, Amgen. **9.** Centers for Medicare & Medicaid Services. 2018 Alpha-Numeric HCPCS File. https://www.cms.gov/medicare/coding/hcpcsreleasecodesets/alpha-numeric-hcpcs-items/2018-alpha-numeric-hcpcs-file-.html. Accessed February 18, 2019. **10.** American Medical Association. 2017 Professional Edition, Current Procedural Terminology (CPT). Copyright 2016 American Medical Association. 2017. All rights reserved. **11.** CMS. ICD-10-CM Official Guidelines for Coding and Reporting, FY 2017. http://www.cdc.gov/nchs/data/icd/10cmguidelines_2017_final.pdf. Accessed January 24, 2019. **12.** Centers for Disease Control and Prevention. International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM). 2017 ICD-10-CM tabular list of diseases and injuries. FY 2017. Tabular list. ftp://ftp.cdc.gov. Accessed January 24, 2019. **13.** American Medical Association. Identifying and Appealing Health Insurance Claim Payment Issues. 2015. **14.** Select Health of South Carolina. *Health Care Professional and Provider Manual.* Charleston, SC: Select Health of South Carolina; 2019. **15.** Centers for Medicare and Medicaid Services. *Medicare & You. The Official U.S. Government Medicare Handbook.* Baltimore, MD: Centers for Medicare and Medicaid Services; 2018. **16.** Centers for Medicare & Medicaid Services. Medical Learning Network Medicare Parts A & B Appeals Process. ICN 006562 May 2016. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedicareAppealsProcessTextOnly.pdf. Accessed January 24, 2019. **17.** Aetna. Health care professionals: Dispute process FAQs. https://www.aetna.com/faqs-health-insurance/health-care-professionals-dispute-process-faqs.html. Accessed January 24, 2019. **18.** Humana. Claim payment reconsiderations and appeals. https://www.humana.com/provider/medicalproviders/education/claims/reconsiderations-and-appeals. Accessed January 24, 2019. **19.** Data on file, Amgen. 2019.

prolia® (denosumab) injection

Amgen Assist® gives you support throughout the reimbursement process, so you can choose the service that's right to help your patients

- Insurance Verification
- Referral to Alternate Site of Care Support
- Financial Assistance Options
- Prolia® Field Reimbursement Specialists

For more information about Amgen Assist®, visit AmgenAssistSupport.com or call 1-866-AMG-ASST (1-866-264-2778), Monday through Friday, 9:00 am to 8:00 pm ET

- The materials in this presentation are intended to provide a broad overview of very complex and evolving programs and issues related to Amgen's products. This information is not intended to serve as specific advice or direction on how to utilize, bill, or charge for any product or service. A healthcare practitioner should make the ultimate determination as to when to prescribe a specific product for an individual patient
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