



Your Journey Toward Stronger Bones:

A Guide to Managing Your Postmenopausal Osteoporosis

Indication

Prolia[®] is a prescription medicine used to treat osteoporosis in women after menopause who are at high risk for fracture or cannot use another osteoporosis medicine or other osteoporosis medicines did not work well.

Important Safety Information

What is the most important information I should know about Prolia[®]?

If you receive Prolia, you should not receive XGEVA[®] (denosumab). Prolia contains the same medicine as XGEVA[®].

Prolia[®] can cause serious side effects (including):

Increased risk of severe low calcium levels in your blood (hypocalcemia). Prolia may lower the calcium levels in your blood. If you have low blood calcium before you start receiving Prolia, it may get worse during treatment. Your low blood calcium must be treated before you receive Prolia. Talk to your doctor before starting Prolia. Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood while you take Prolia. Take calcium and vitamin D as your doctor tells you to.

If you have advanced chronic kidney disease (may or may not be on kidney dialysis), Prolia may increase your risk for severe low calcium levels in your blood, which could result in hospitalization, life-threatening events and death. A mineral and bone disorder associated with kidney disease called chronic kidney disease-mineral bone disorder (CKD-MBD) may increase your risk for severe low calcium levels in blood. Before you start PROLIA and during treatment, your doctor may need to do certain blood tests to check for CKD-MBD.

Please see additional Prolia[®] Important Safety Information on pages 10-11.

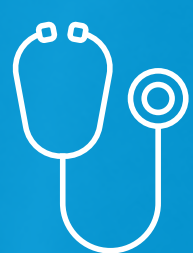


prolia[®]
(denosumab) injection

Let's map **your journey together.**

This kit helps you understand why osteoporosis treatment matters and what personal plan makes sense for you.

Patient instructions: Discuss your personal plan with your doctor, and review the rest of this kit as you work together to map your treatment journey.



Healthcare provider instructions: Start by filling out the fields and plotting the T-score chart on page 4 with your patient.

The impact from a broken bone can include potentially devastating consequences

What are the risks of not treating osteoporosis?

Risks of Not Treating Postmenopausal Osteoporosis

5X

After you break a bone, you are **5 times more likely** to break another bone within a year²

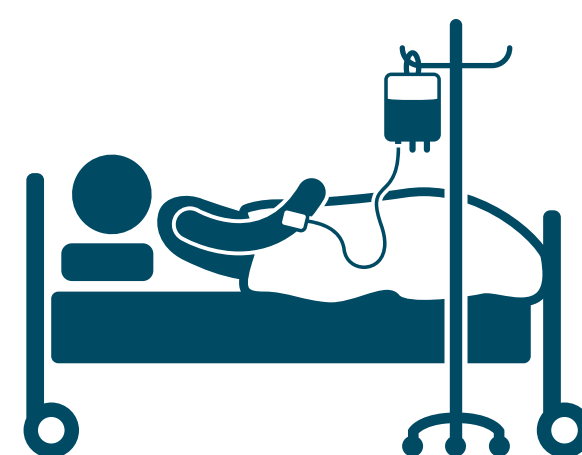
Potential Impact of Broken Bones



A move to a nursing home or **long-term care** facility¹



Pain from fracture³

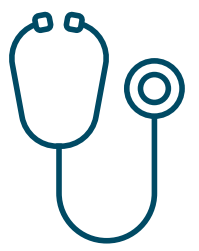


Potential complications during hospitalization (due to hip fracture)⁴



Potential burden on patients, their families, and their finances^{5,6}

References: **1.** US Department of Health and Human Services. Bone health and osteoporosis: a report of the surgeon general. 2004. Rockville, MD. **2.** van Geel TA, van Helden S, Geusens PP, Winkens B, Dinant GJ. Clinical subsequent fractures cluster in time after first fractures. *Ann Rheum Dis.* 2009;68(1):99-102. **3.** National Osteoporosis Foundation. *Clinician's Guide to Prevention and Treatment of Osteoporosis.* Washington, DC: National Osteoporosis Foundation; 2014. **4.** Inacio MC, Weiss JM, Miric A, Hunt JJ, Zohman GL, Paxton EW. A Community-Based Hip Fracture Registry: Population, Methods, and Outcomes. *Perm J.* 2015;19(3):29-36. **5.** Royal Osteoporosis Society. Life with Osteoporosis 2021: the untold story. <https://strwebprdmedia.blob.core.windows.net/media/1d5hdsg4/life-with-osteoporosis-2021-public-report-final-1.pdf>. Accessed February 14, 2024. **6.** Hansen D, Bazell C, Pelizzari P, Pyenson B. Milliman Research Report. <https://www.milliman.com/en/insight/medicare-cost-of-osteoporotic-fractures-2021-updated-report>. Accessed February 14, 2024.



Healthcare provider instructions: Fill out the following fields and plot the chart. Use the **lowest** T-score identified by the DXA scan.¹

Are you at risk of **breaking a bone?**

Risk factors for fracture:^{2,3}

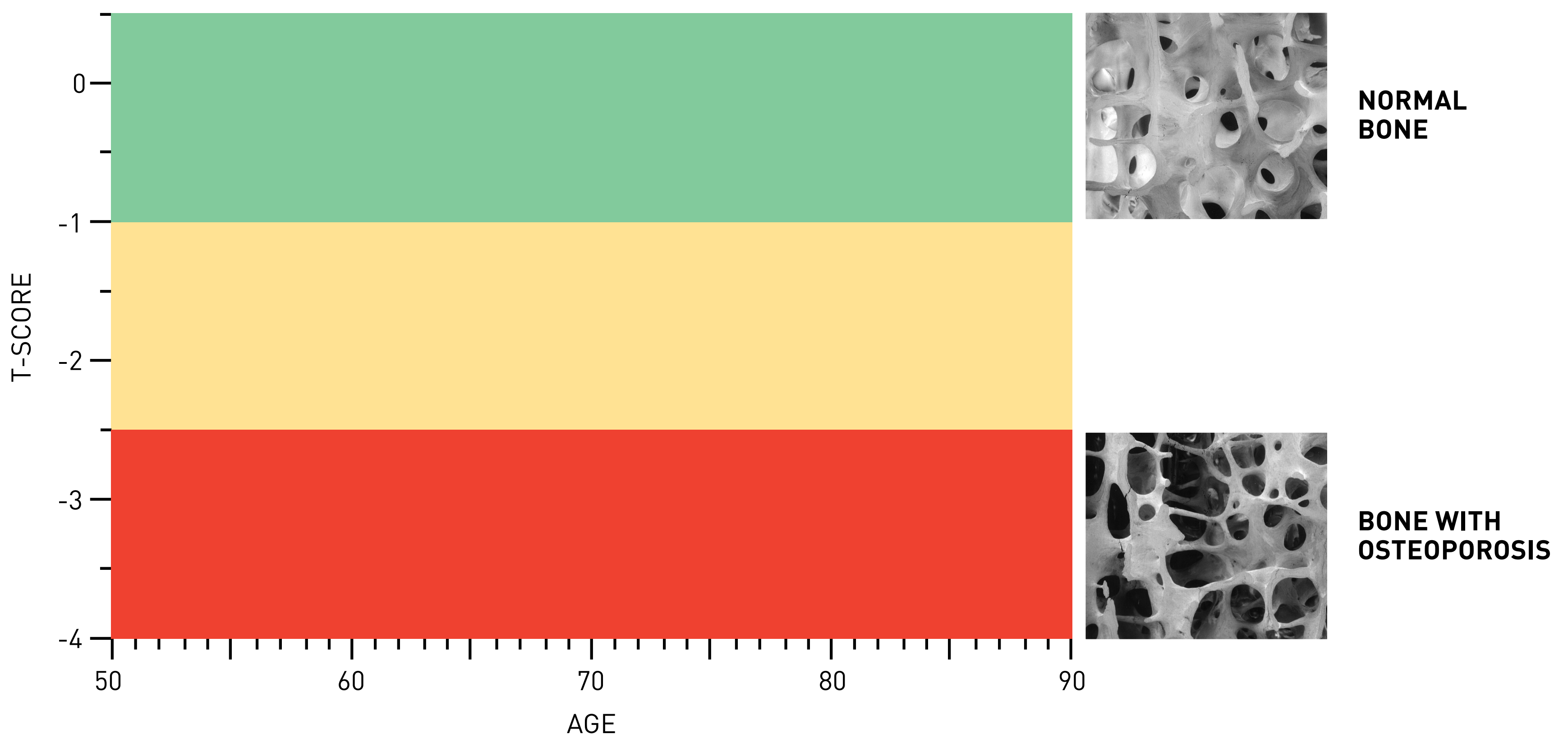
- | | |
|--|---|
| <input type="checkbox"/> Low bone density (T-score less than or equal to -2.5) | <input type="checkbox"/> Parental history of broken hip |
| <input type="checkbox"/> Age 65 or older | <input type="checkbox"/> Cigarette smoking |
| <input type="checkbox"/> Low body weight | <input type="checkbox"/> Rheumatoid arthritis |
| <input type="checkbox"/> Previous fracture | <input type="checkbox"/> Diabetes |
| <input type="checkbox"/> Long-term steroid use | <input type="checkbox"/> Risk of falling |
| <input type="checkbox"/> Excessive alcohol >3 drinks/day | |

T-score is a measure of bone density, which helps determine the severity of osteoporosis and your risk for fracture.¹ Let's look at your T-score.

T-score site: _____

▲ Prior T-score: _____ Date: _____

● Current T-score: _____ Date: _____



Bone images courtesy of David W. Dempster, PhD, 2000. Reproduced with permission.

References: **1.** Baniak N, Grzybowski S, Olszynski WP. Dual-energy x-ray absorptiometry scan autoanalysis vs manual analysis. *J Clin Densitom.* 2014;17(1):97-103. **2.** National Osteoporosis Foundation. *Clinician's Guide to Prevention and Treatment of Osteoporosis.* Washington, DC: National Osteoporosis Foundation; 2014. **3.** Kanis JA, Black D, Cooper C, et al. A new approach to the development of assessment guidelines for osteoporosis. *Osteoporos Int.* 2002;13(7):527-536.

Exercise, calcium, and vitamin D can help but may not be sufficient to protect your bones. Prescription treatment can help reduce your risk for fracture.

Introducing Prolia[®] treatment

What is Prolia[®]?

Prolia[®] is a prescription medicine used to treat osteoporosis in women after menopause who are at high risk for fracture or cannot use another osteoporosis medicine or other osteoporosis medicines did not work well.

How does it work?

Prolia[®] slows the loss of bone by stopping bone-removing cells before they can reach and damage the bone. Prolia[®] also helps to strengthen your bones.

How is it taken?

Prolia[®] is one shot every 6 months given by a healthcare professional. You should take calcium and vitamin D as your doctor tells you to while you receive Prolia[®]. After your treatment with Prolia is stopped, or if you skip or delay taking a dose, your risk for breaking bones, including bones in your spine, is increased. Do not stop, skip or delay taking Prolia[®] without first talking with your doctor.



The image above is for illustration purposes only and represents a snapshot in time. Actual dosing and duration of a particular patient's therapy should be based upon the product's approved labeling and independent clinical decision of the provider.

Important Safety Information

Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your doctor right away if you have symptoms of low blood calcium such as:

- spasms, twitches, or cramps in your muscles
- numbness or tingling in your fingers, toes, or around your mouth

Reference: Prolia[®] (denosumab) prescribing information, Amgen.

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



For women with osteoporosis after menopause who are at high risk for fracture

What are the **benefits of Prolia® (denosumab)?**

In a 3-year clinical study, women with postmenopausal osteoporosis taking Prolia® reduced their risk of new spine fractures by 68%.^{1,2}



REDUCED RISK
OF NEW SPINE
FRACTURES BY

68%^{1,2}

In a 3-year study in which patients received either Prolia® or placebo (a treatment containing no medicine), women treated with Prolia® had fewer new spine fractures (2.3%) compared to women not treated with Prolia® (7.2%).^{1,2}

Additional results from the 3-year study proved that Prolia®:

- Significantly reduces fractures of the spine (by 68%), hip (by 40%), and other bones (by 20%)
 - Women not treated with Prolia® had more hip fractures (1.2%) compared to women treated with Prolia® (0.7%). In other parts of the body, women not treated with Prolia® had more bone fractures (8.0%) compared to women treated with Prolia® (6.5%).^{1,2}
- Helps increase bone density by 8.8% in the spine, 9.4% Prolia® vs 0.6% placebo^{1,3}
- Helps make bones stronger with 1 shot every 6 months¹

Important Safety Information

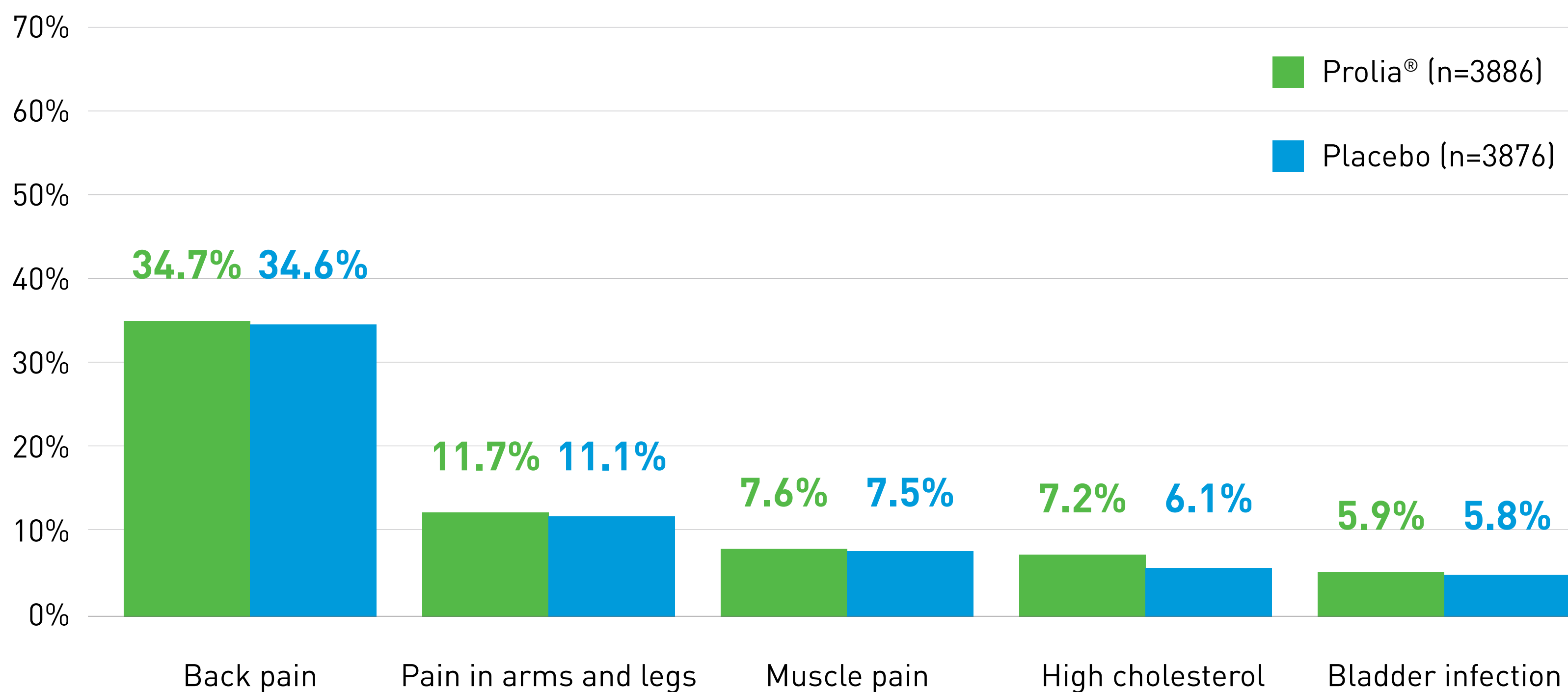
You should take calcium and vitamin D as your doctor tells you to while you receive Prolia®. After your treatment with Prolia® is stopped, or if you skip or delay taking a dose, your risk for breaking bones, including bones in your spine, is increased. Do not stop, skip or delay taking Prolia® without first talking with your doctor.

References: 1. Prolia® (denosumab) prescribing information, Amgen. 2. Cummings SR, San Martin J, McClung MR, et al. Denosumab for prevention of fractures in postmenopausal women with osteoporosis. *N Engl J Med.* 2009;361(8):756-765. 3. Data on file, Amgen; 2008.

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

What are the possible side effects of Prolia®?

In this study, the following side effects happened among more than 5% of Prolia® patients and more frequently than in placebo-treated patients.¹



Serious side effects

Prolia® can cause serious side effects. Possible serious side effects include serious allergic reactions, low blood calcium, severe jaw bone problems, unusual thigh bone fractures, increased risk of broken bones, including broken bones in the spine, after stopping, skipping or delaying Prolia®, serious infections, skin problems, and severe bone, joint, or muscle pain.¹

In the 3-year clinical study, serious side effects reported at a rate greater than placebo included low blood calcium (1.7% vs 0.4% for Prolia® and placebo, respectively), nonfatal serious infections (4.0% vs 3.3%, respectively), and skin problems (10.8% vs 8.2%, respectively). Also observed in the 3-year study, 6% of women who discontinued Prolia® and remained in the study developed new vertebral fractures, and 3% of women who discontinued Prolia® and remained in the study developed multiple new vertebral fractures.¹

After the 3-year study, patients on Prolia® were followed for up to an additional 7 years, where the following were observed:

Severe jawbone problems (ONJ) at a rate of 30 in 10,000 patients (0.3%) ²	⋮	Unusual thighbone breaks (AFF) at a rate of 4 in 10,000 patients (0.04%) ²
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ONJ = osteonecrosis of the jaw; AFF = atypical femoral fracture.

In the 3-year study, patients and their providers did not know if they were receiving Prolia® or placebo. In the 7-year follow-up period, patients and their providers knew they were receiving Prolia®; this study design has the potential for introducing bias in reporting symptoms.²

References: 1. Prolia® (denosumab) prescribing information, Amgen. 2. Bone HG, Wagman RB, Brandi ML, et al. 10 years of denosumab treatment in postmenopausal women with osteoporosis: results from the phase 3 randomised FREEDOM trial and open-label extension. *Lancet Diabetes Endocrinol.* 2017;5(7):513-523.



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

Prolia® (denosumab)

Frequently Asked Questions



How long has Prolia® been on the market?

Prolia® was FDA approved in 2010.¹



How long has Prolia® been studied?

Prolia® has been studied in patients who were on therapy for up to 10 years.²



Will Prolia® help me strengthen my bones?

90% of patients taking Prolia® saw a meaningful increase in bone density in their spine (>3%) at the end of the 3-year clinical study. Meaningful being defined as achieving a bone density increase (>3%) that a doctor would conclude is a significant change in bone density as a result of treatment.³

You can find out what your bone density T-score is by taking a bone scan called a DXA (pronounced dexa) scan that is prescribed by your healthcare provider every 1-2 years.³



How long do I need to take Prolia®?

When you have postmenopausal osteoporosis, your bones may no longer be able to maintain their strength on their own.^{4,5}

Talk to your doctor about a specific treatment plan that is right for you.

Working towards stronger bones means starting and staying on treatment as directed by your doctor.

In a clinical study, Prolia® continued to help strengthen bone in the spine and hip in patients on treatment at 10 years.²



How long will Prolia® stay in my body?

In a 3-year clinical trial, the Prolia® concentration in the blood was measured frequently:⁶

- After 25.4 days the concentration of Prolia® in the blood was reduced by half
- After 6 months the concentration of Prolia® in the blood was undetectable. That's why it's important to get your shot of Prolia® every 6 months

Prolia® only works when you take it as prescribed by your healthcare provider. After your treatment with Prolia® is stopped, or if you skip or delay taking a dose, your risk for breaking bones, including bones in your spine, is increased. Do not stop, skip or delay taking Prolia® without first talking with your doctor.



Do many people stop taking Prolia® due to side effects?

In the 3-year clinical study among 3,886 postmenopausal women with osteoporosis on Prolia®, 2.4% of people withdrew from the study due to adverse events.⁶



Does my insurance pay for Prolia®?

The majority of Medicare and commercial plans cover Prolia®.⁷ What you pay will depend on your insurance. To learn more go to: www.prolia.com/paying-for-prolia.

DXA, dual energy X-ray absorptiometry; FDA, Food and Drug Administration.

Please see Indication & Important Safety Information on pages 10-11.

References: **1.** Prolia® (denosumab) FDA approval letter. June 1, 2010. **2.** Bone HG, Wagman RB, Brandi ML, et al. 10 years of denosumab treatment in postmenopausal women with osteoporosis: results from the phase 3 randomised FREEDOM trial and open-label extension. *Lancet Diabetes Endocrinol.* 2017;5(7):513-523. **3.** Bolognese MA, Teglbjærg CS, Zanchetta JR, et al. Denosumab significantly increases DXA BMD at both trabecular and cortical sites: results from the FREEDOM study. *J Clin Densitom.* 2013;16(2):147-153. **4.** Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis - 2016. *Endocr Pract.* 2016;22(Suppl 4):1-42. **5.** National Osteoporosis Foundation. *Clinician's Guide to Prevention and Treatment of Osteoporosis.* Washington, DC: National Osteoporosis Foundation; 2014. **6.** Prolia® (denosumab) prescribing information, Amgen. **7.** Data on file, Amgen; 2022.

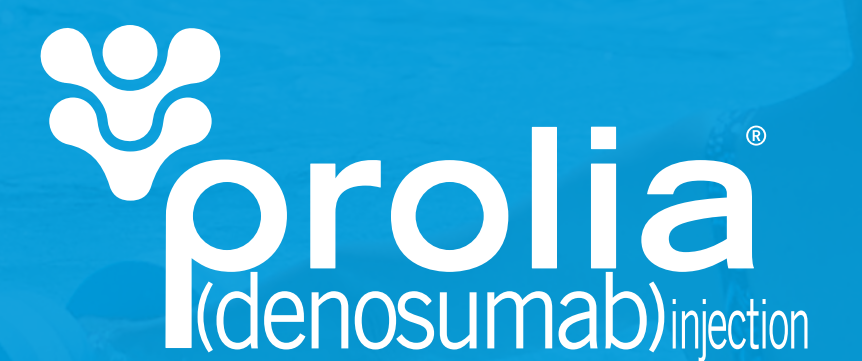
Important locations

DXA scan: _____

Lab work: _____

Injection clinic: _____

Please see Indication & Important Safety Information
on pages 10-11.



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If you have advanced chronic kidney disease (may or may not be on kidney dialysis), Prolia may increase your risk for severe low calcium levels in your blood, which could result in hospitalization, life-threatening events and death. A mineral and bone disorder associated with kidney disease called chronic kidney disease-mineral bone disorder (CKD-MBD) may increase your risk for severe low calcium levels in blood. Before you start PROLIA and during treatment, your doctor may need to do certain blood tests to check for CKD-MBD.

Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your doctor right away if you have symptoms of low blood calcium such as:

- spasms, twitches, or cramps in your muscles
- numbness or tingling in your fingers, toes, or around your mouth

Serious allergic reactions have happened in people who take Prolia®. Call your doctor or go to your nearest emergency room right away if you have any symptoms of a serious allergic reaction, including low blood pressure (hypotension); trouble breathing; throat tightness; swelling of your face, lips, or tongue; rash; itching; or hives.

Severe jaw bone problems (osteonecrosis) may occur. Your doctor should examine your mouth before you start Prolia® and may tell you to see your dentist. It is important for you to practice good mouth care during treatment with Prolia®.

Unusual thigh bone fractures. Some people have developed unusual fractures in their thigh bone. Symptoms of a fracture include new or unusual pain in your hip, groin, or thigh.

Increased risk of broken bones, including broken bones in the spine, after stopping, skipping or delaying Prolia®. Talk with your doctor before starting Prolia® treatment. After your treatment with Prolia® is stopped, or if you skip or delay taking a dose, your risk for breaking bones, including bones in your spine, is increased. Your risk for having more than 1 broken bone in your spine is increased if you have already had a broken bone in your spine. Do not stop, skip or delay taking Prolia® without first talking with your doctor. If your Prolia® treatment is stopped, talk to your doctor about other medicine that you can take.

Important Safety Information (continued)

Serious infections in your skin, lower stomach area (abdomen), bladder, or ear may happen. Inflammation of the inner lining of the heart (endocarditis) due to an infection may also happen more often in people who take Prolia®. You may need to go to the hospital for treatment.

Prolia® is a medicine that may affect the ability of your body to fight infections. People who have weakened immune systems or take medicines that affect the immune system may have an increased risk for developing serious infections.

Skin problems such as inflammation of your skin (dermatitis), rash, and eczema have been reported.

Bone, joint, or muscle pain. Some people who take Prolia® develop severe bone, joint, or muscle pain.

Do not take Prolia® if you: have low blood calcium; or are pregnant or plan to become pregnant, as Prolia® may harm your unborn baby; or are allergic to denosumab or any ingredients in Prolia®.

Before taking Prolia®, tell your doctor about all of your medical conditions, including if you:

- Take the medicine XGEVA® (denosumab).
- Have low blood calcium
- Cannot take daily calcium and vitamin D
- Had parathyroid or thyroid surgery (glands located in your neck)
- Have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome)
- Have kidney problems or are on kidney dialysis
- Are taking medicine that can lower your blood calcium levels
- Plan to have dental surgery or teeth removed
- Are pregnant or plan to become pregnant.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with Prolia®.
- You should use an effective method of birth control (contraception) during treatment with Prolia® and for at least 5 months after your last dose of Prolia®.
- Tell your doctor right away if you become pregnant while taking Prolia®.
- Are breast-feeding or plan to breast-feed

What are the possible side effects of Prolia®?

It is not known if the use of Prolia® over a long period of time may cause slow healing of broken bones. The most common side effects of Prolia® are back pain, pain in your arms and legs, high cholesterol, muscle pain, and bladder infection.

These are not all the possible side effects of Prolia®. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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



Prolia.com and Other Resources to Learn About Osteoporosis

Prolia®: www.prolia.com

Bone Health & Osteoporosis Foundation: www.bonehealthandosteoporosis.org

American Bone Health: www.americanbonehealth.org

Note: The list of resources and links above is not exhaustive. Some of these resources and links were created by independent third parties and Amgen does not endorse any of these resources or the entities sponsoring these links.



Please see Indication & Important Safety Information on pages 10-11.

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USA-162-83539 02/24

 **prolia**®
(denosumab) injection

Starting Your Journey All About You



Name: _____

Date: _____

In order to determine the best osteoporosis treatment plan for you, let's review your life needs and goals.

1. Tell me about your responsibilities; are you?

- Working
- Retired
- Taking care of a spouse/partner or other family members
- Other: _____

2. What does a good day look like for you? What do you love to do?

3. Have you been treated for osteoporosis in the past? Yes No

If so, what medication? _____

How long were you on it? _____

4. If you have any specific concerns about getting onto a prescription osteoporosis treatment, what are they?

- How well it works
- How it is taken and how often
- Side effects
- Cost
- Other concerns: _____

Your Personal Postmenopausal Osteoporosis Treatment Plan



Date: _____

Based on our discussion today, your risk factors, and your T-score, my recommendation for treatment of your postmenopausal osteoporosis is as follows:

Medication: _____

Dosing: _____

Supplements:

Calcium: _____ mg

Vitamin D: _____ IU

Dietary Sources: _____

Exercise: _____ minutes/daily/weekly

Weights

Walking

Yoga

Other _____

Fall prevention tips:

Wear sensible shoes

Remove home hazards

Light up your living space

Use assistive devices

Follow-up DXA scan date: _____

Return visit date: _____

Lab work follow-up date: _____

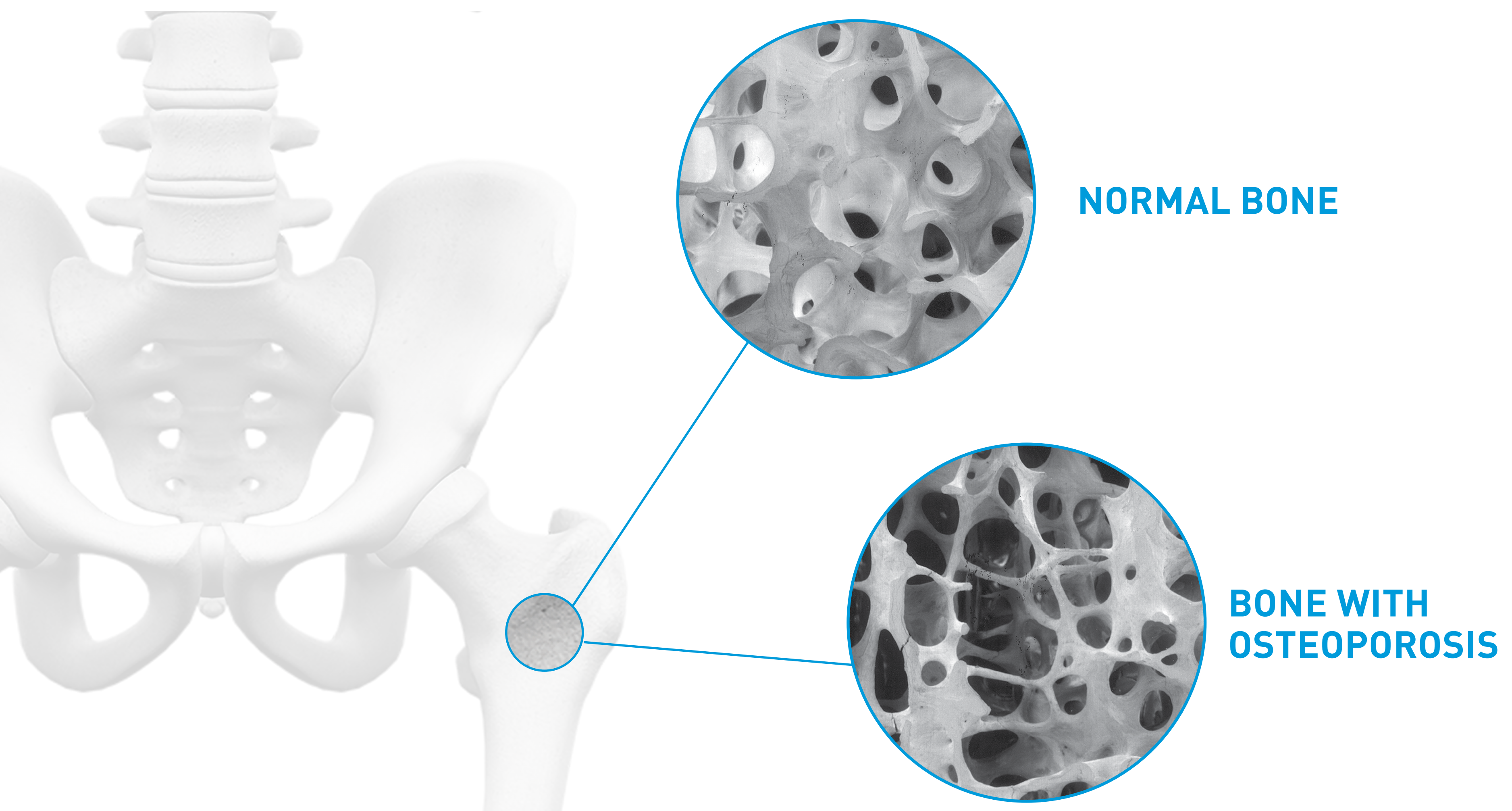
Notes: _____

What Is Osteoporosis?

Osteoporosis is a bone disease that occurs when your body loses too much bone, makes too little bone, or both. As a result, bones become weak and may break from a fall or minor bumps.¹

Osteoporosis is often called a silent disease because you can't feel bones weakening. Breaking a bone is often the first sign of osteoporosis.²

Some genetic and lifestyle factors might have contributed to your osteoporosis, such as a family history of hip fracture; a small, thin body frame; or your eating and exercise habits.¹



Bone images courtesy of David W. Dempster, PhD, 2000. Reproduced with permission.

There are cells that build bones and cells that remove bone. After menopause, as your estrogen levels decline, the bone removers become more active, creating an imbalance favoring bone loss. There are osteoporosis treatments that can help restore the balance between these two types of cells.¹

Osteoporosis isn't an inevitable part of aging. You can manage your osteoporosis through prescription treatment and lifestyle changes to help reduce your risk of fracture.

References: **1.** National Osteoporosis Foundation. *Clinician's Guide to Prevention and Treatment of Osteoporosis*. Washington, DC: National Osteoporosis Foundation; 2014. **2.** National Institute on Aging. <https://www.nia.nih.gov/health/osteoporosis>. Accessed February 14, 2024.