



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

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[®].

Please see additional important safety information on pages 10-11.



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?

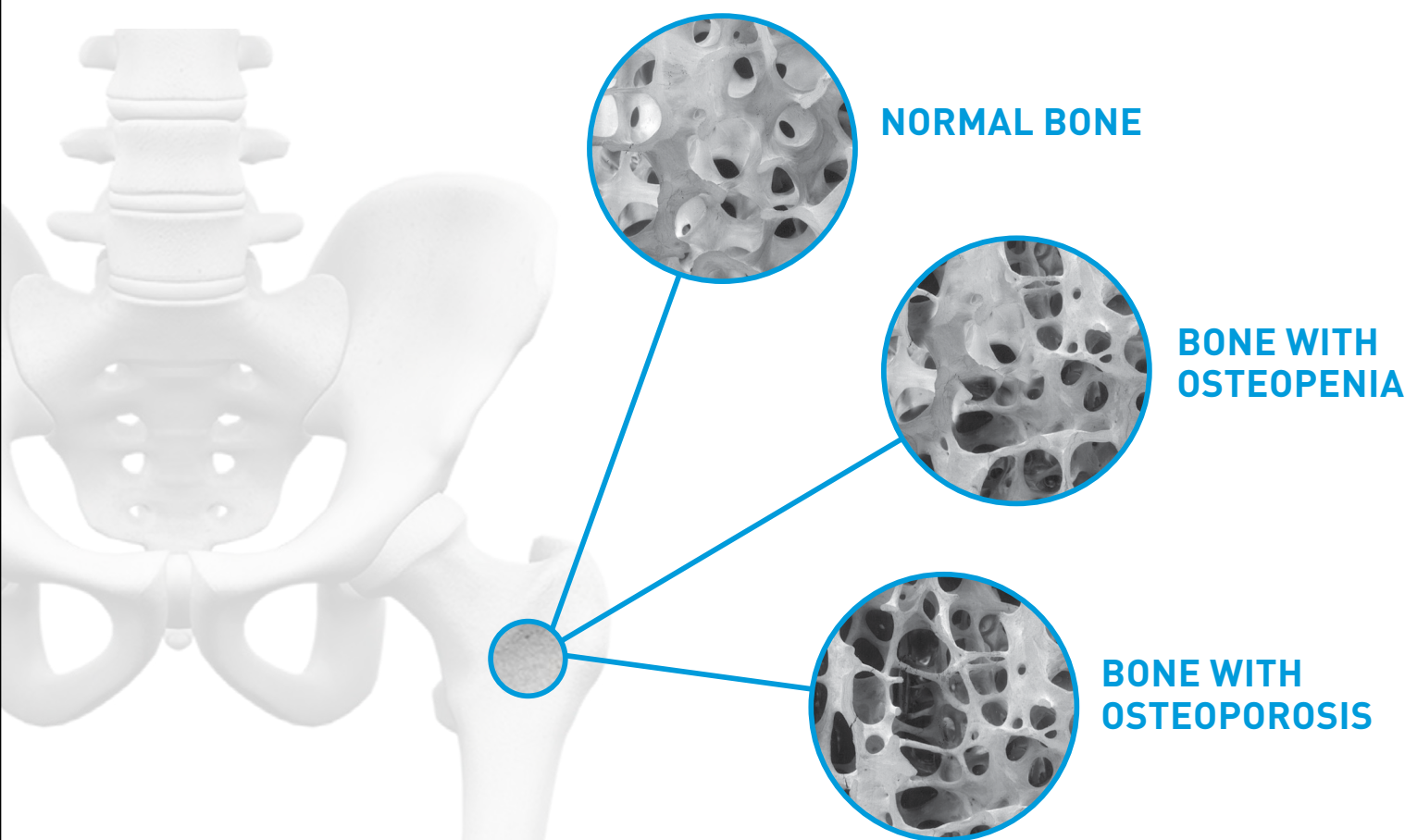
- How well it works
- How it is taken and how often
- Side effects
- Cost
- Other concerns: _____

What Is Osteoporosis?

Osteoporosis (“porous bone”) 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.

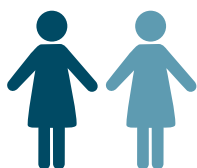
There are cells that build bones and cells that remove bone. After menopause, as your estrogen levels decline, the bone removers become more active, creating an imbalance favoring bone loss. There are osteoporosis treatments that can help restore the balance between these two types of cells.¹

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 April 15, 2020.

What are the risks of not treating osteoporosis?

Risks of Not Treating Postmenopausal Osteoporosis



1 in 2 women over age 50 will break a bone because of osteoporosis¹

5X

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

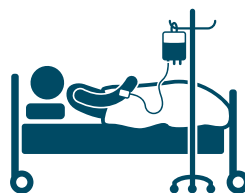
Potential Impact of Broken Bones



A move to a nursing home or **long-term care facility**¹



Pain from fracture³



Potential complications during hospitalization (due to hip fracture)⁴



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

Exercise, calcium, and vitamin D can help but may not be sufficient to protect your bones.¹ Prescription treatment can help reduce your risk further.

References: **1.** US Department of Health and Human Services. *Bone Health and Osteoporosis: A Report of the Surgeon General*. Rockville, MD: US Department of Health and Human Services. Office of the Surgeon General; 2004. **2.** van Geel TA, et al. *Ann Rheum Dis*. 2009;68:99-103. **3.** Cosman F, de Beur SJ, Leboff MS, et al. *Clinician's Guide to Prevention and Treatment of Osteoporosis*. *Osteoporos Int*. 2014;25:(10):2359-2381. **4.** Inacio MCS, et al. *Perm J*. 2015;19:29-36. **5.** National Osteoporosis Society. Life with osteoporosis. October 2014. <https://nos.org.uk/media/1859/life-with-osteoporosis.pdf>. Accessed April 15, 2020. **6.** Hansen D, Bazell C, Pelizzari P, Pyenson, B. Medicare cost of osteoporotic fractures: The clinical and cost burden of an important consequence of osteoporosis. Milliman Research Report. 2019;1-48.



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?**

Do you have 2 or more of these risk factors? If so, you may be at high risk for osteoporotic fracture.²⁻⁴

- T-score less than -2.5
- Being over age 65
- Small, thin body frame
- Previous broken bone as an adult
- Family history of broken hip
- Cigarette smoking
- Inactive lifestyle
- Steroid usage

T-score is a measure of bone density, which helps determine the severity of osteoporosis and your risk for fracture.⁵ Let's look at your T-score.

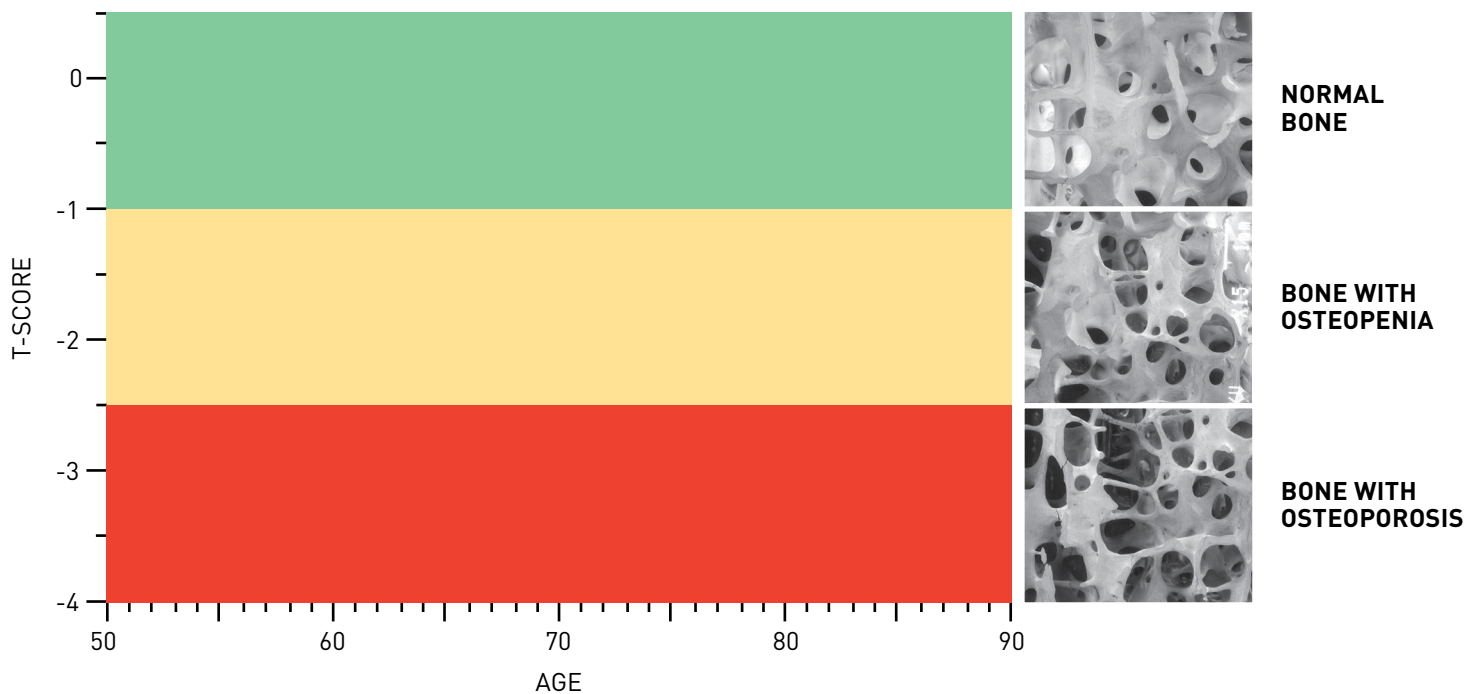
T-score site: _____

▲ Prior T-score: _____

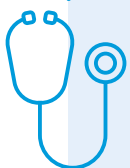
Date: _____

● Current T-score: _____

Date: _____



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



Based on my clinical judgment, your risk factors, and your T-score or prior osteoporosis-related fracture, I recommend that you:

- Start prescription treatment
- Continue to monitor bone density

References: 1. Baniak N, et al. *J Clin Denistom.* 2014;17:97-103. 2. National Osteoporosis Foundation. *Clinician's Guide to Prevention and Treatment of Osteoporosis.* Washington, DC: National Osteoporosis Foundation; 2014. 3. Kanis JA, et al. *Osteoporos Int.* 2002;13:527-536. 4. Prolia® (denosumab) prescribing information, Amgen. 5. Camacho PM, et al. *Endocr Pract.* 2016;22(suppl 4):1-42.

Common osteoporosis treatment options

Osteoporosis Treatment	Prolia® (denosumab) ¹	Oral Bisphosphonates ^{2,3}	Intravenous Bisphosphonates ^{4,5}	Anabolics ⁶⁻⁸
How does it work?	Slows bone loss A targeted treatment that helps stop bone-removing cells, leading to less bone loss	Slows bone loss Binds to bone where it helps stop bone-removing cells, leading to less bone loss	Slows bone loss Binds to bone where it helps stop bone-removing cells, leading to less bone loss	Builds bone Increases the level of activity of bone-building cells
How often do I take it?	Once every 6 months	Once daily or Once weekly or Once monthly	Once yearly or Once every 3 months	Once daily or Once monthly
How do I take it?	Injection by your healthcare professional	Oral tablet or Oral solution	Intravenous infusion or Intravenous injection	Self-administered injection or Injection by your healthcare professional

PTH = parathyroid hormone.

The explanation of how the osteoporosis treatments work is not meant to imply that one product works better than another. Safety and efficacy information cannot be compared, due to different study populations and clinical trial designs. Refer to individual product prescribing information for further details.

References: **1.** Prolia® (denosumab) prescribing information, Amgen. **2.** Fosamax® (alendronate) prescribing information, Merck. **3.** Boniva® (ibandronate) prescribing information, Genentech. **4.** Boniva® (ibandronate) Injection prescribing information, Genentech. **5.** Reclast® (zoledronic acid) prescribing information, Novartis. **6.** Forteo® (teriparatide) prescribing information, Eli Lilly. **7.** Tymlos® (abaloparatide) prescribing information, Radius Health. **8.** US Food and Drug Administration. FDA approves new treatment for osteoporosis in postmenopausal women at high risk of fracture. www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-osteoporosis-postmenopausal-women-high-risk-fracture. Accessed April 15, 2020.

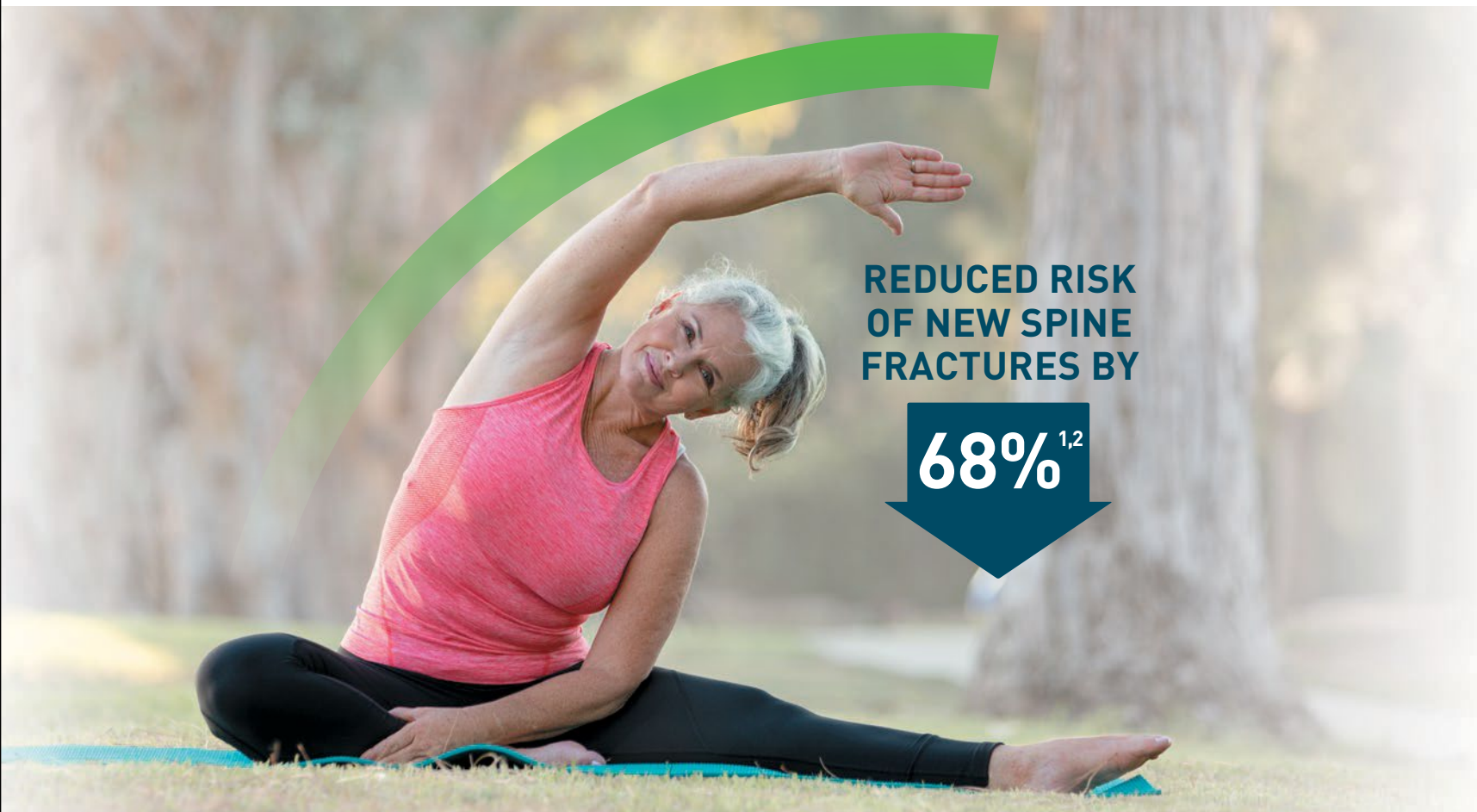


For women with osteoporosis after menopause who are at high risk for fracture

Introducing Prolia®:

What are the benefits of Prolia®?

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

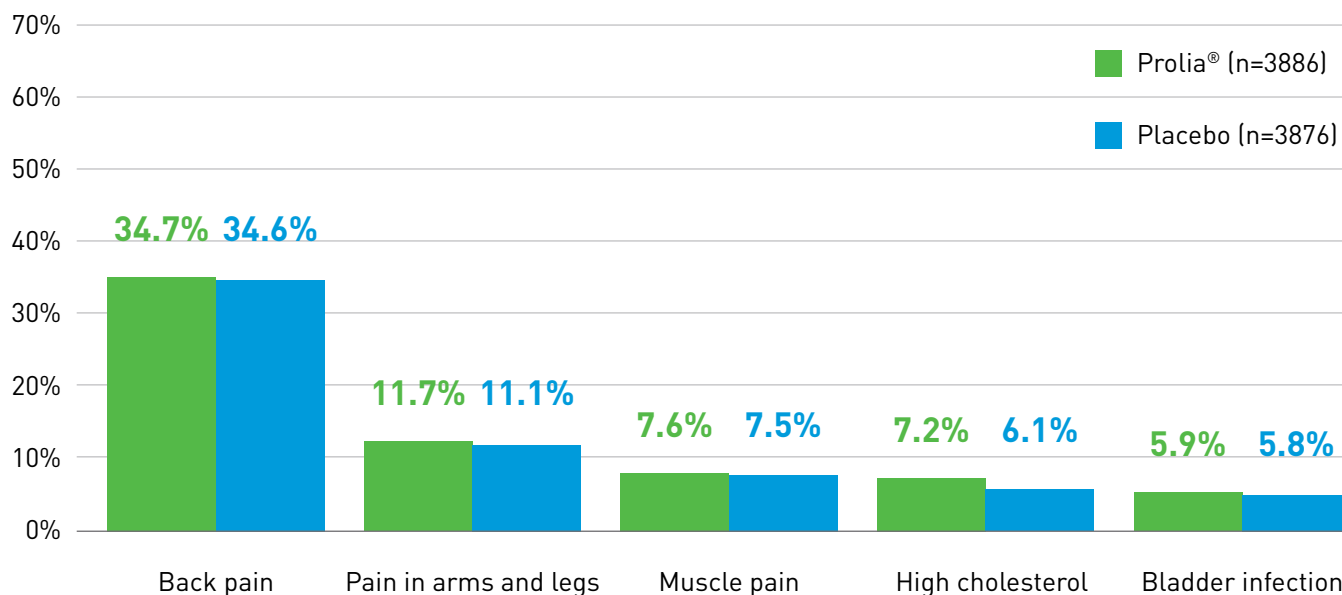
You should take calcium and vitamin D as your doctor tells you to while you receive Prolia®. After your treatment with Prolia® is stopped, or if you skip or delay taking a dose, your risk for breaking bones, including bones in your spine, is increased. Do not stop, skip or delay taking Prolia® without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

To learn more about Prolia®, visit Prolia.com

References: 1. Prolia® (denosumab) prescribing information, Amgen. 2. Cummings SR, et al. *N Engl J Med.* 2009;361:756-765. 3. Data on file, Amgen. 2008.

What are the possible side effects of Prolia®?

In this study, the following side effects happened among more than 5% of patients (or were more common than those who were on placebo).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.

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), 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, et al. *Lancet Diabetes Endocrinol.* 2017;5:513-523.



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 More than 8 million doses of Prolia® have been distributed since 2010.²

How long has Prolia® been studied?

Prolia® has been studied in patients who were on therapy for up to 10 years.³

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.⁴

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.⁵

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.⁶

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.³

How long will Prolia® stay in my body?

In a 3-year clinical trial, the Prolia® concentration in the blood was measured frequently¹:

- 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®, over 90% of women remained on Prolia® until the end of the study. 2.4% of people withdrew from the study due to adverse events.¹

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.

References: 1. Prolia® (denosumab) FDA approval letter. June 1, 2010. 2. Data on file, Amgen. 2019. 3. Bone HG, et al. *Lancet Diabetes Endocrinol.* 2017;5:513-523. 4. Bolognese MA, et al. *J Clin Densitom.* 2003;16:147-153. 5. Camacho PM, et al. *Endocr Pract.* 2016;22 (suppl 4):1-42. 6. National Osteoporosis Foundation. *Clinician's Guide to Prevention and Treatment of Osteoporosis.* Washington, DC: National Osteoporosis Foundation; 2014. 7. Data on file, Amgen. 2018.

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

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®.

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

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

Prolia® can cause serious side effects:

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.

Low blood calcium (hypocalcemia). Prolia® may lower the calcium levels in your blood. If you have low blood calcium, it may get worse during treatment. Your low blood calcium must be treated before you receive Prolia®.

Take calcium and vitamin D as your doctor tells you to help prevent low blood calcium.

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.

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.

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 accompanying Prolia[®] full [Prescribing Information](#), including [Medication Guide](#).

Prolia.com and Other Resources to **Learn About Osteoporosis**

Prolia®: www.prolia.com

National Osteoporosis Foundation: www.nof.org/patients

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.



AMGEN®

 **prolia®**
(denosumab) injection

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: _____





Fracture Prevention for Daily Activities

Performing daily activities correctly is just as important as choosing the right exercises if you have low bone density. Try the postures below or view the video tutorials to see if you are performing your everyday activities correctly!

Fracture Prevention Tips:

● **Spine Protection**

Avoid rounding forward and excessive twisting

● **Hip + Wrist Protection**

Practice balance and standing on one leg regularly to prevent falls

If you have low bone density, you may be at risk for fracture:

● Strengthening the muscles of your mid-back and legs has been shown to be most effective for building bone and fracture prevention.

● **Posture and Balance Exercises**

Posture correction and dynamic balance challenges have been shown to be effective in fall and fracture prevention.

EVERYDAY ACTIVITIES

Keep your back straight.
Avoid rounding your spine & shoulders.

General Lifting:



Stand with your feet a little wider than your hips, keep knees in line with middle toes as you squat to lift an object. Hinge at the hips, keep the chest lifted, shoulder blades back and down and bring the object as close as possible to you.

Unpacking Groceries:



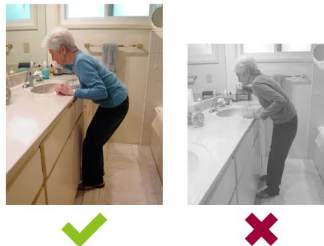
Keep spine lengthened and straight, chest lifted and knees bent. Rest knees against bumper to brace your body. Hinge at the hips instead of rounding the back to reach into trunk. Lift one bag at a time, keep shoulders back and be sure to watch where you are going.

Lifting a Pet:



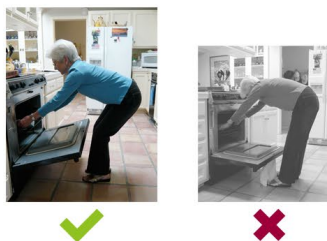
Stand with your feet a little wider than your hips, keep knees in line with middle toes as you squat to lift a pet or child. Hinge at the hips, keep the chest lifted, shoulder blades back and down and bring the pet or child as close as possible to you. Avoid lifting children who can walk.

Brushing Teeth:



Keep spine lengthened and straight, chest lifted and knees bent. Rest knees against bumper to brace your body. Hinge at the hips instead of rounding the back to bend towards the sink.

The Oven:



Keep spine lengthened and straight, chest lifted and knees bent. Hinge at the hips instead of rounding the back to reach into the oven. Use oven mitts for better control of a heavy dish. Drag the dish close to the edge. "Setting" the shoulder blades down and back, draw the object out of the oven.

Washing the Dishes:



Keep spine lengthened and straight, chest lifted and knees bent. Rest knees against bumper to brace your body. Hinge at the hips instead of rounding the back to bend towards the sink.

Making the Bed:



Keep chest lifted, tailbone lifted and brace knees against bed.

Gardening:



Use a pad or sit on a small stool to garden. Hinge at the hips, keeping the chest lifted and the spine straight to reach the ground. When standing, avoid locking the knees and also avoid bending forward at the waist rounding your back to work in your garden.

Driving:



When checking behind, reach right hand behind passenger headrest to brace yourself and keep chest lifted as you rotate.

EXERCISING

Considerations for exercise:

Avoid rounding and twisting your spine.

Core Strengthening:



Avoid all forms of crunches, instead practice core control by drawing in abdominals as you bring one leg at a time to a 90 degree angle and press lower back down. Alternate touching toes to the floor.

Spinal Twisting:



Avoid seated or supine extreme spinal twists. Gently rotate the pelvis and legs keeping shoulder blades on the floor.

Spinal Stretching:



Avoid yoga Forward Fold and Pilates Spine Stretch. Instead do seated chest stretch supported by arms.

Postural Strengthening:



Avoid yoga Cat Stretch and all rounded back stretches. Instead practice "All 4s" opposite arm and leg raises to strengthen upper back and hips.

Spine Strengthening:



Avoid yoga Plough, Shoulder Stand, Pilates Rollover and Jackknife. Instead do yoga Cobra, Pilates Swan or Pilates Modified Double Leg Kick.

Abdominal Strengthening:



Avoid Pilates Rollup and Hundred. Instead do Pilates Single Leg Kick with lower abdominals supporting the back.

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