PACE Pharmaceutical Assistance Contract for the Elderly

Alosa Health
Balanced information for better care

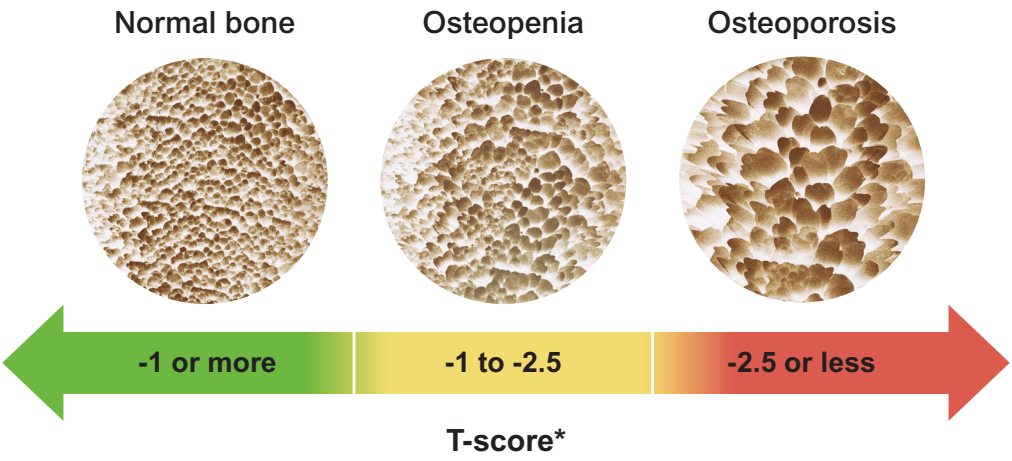
Treating osteoporosis

Effective ways to avoid debilitating fractures

Low bone density is common and treatable

Over 10 million Americans ≥ 50 years old have osteoporosis, and 43 million more have osteopenia—increasing their risk of a life-changing fracture.[1]

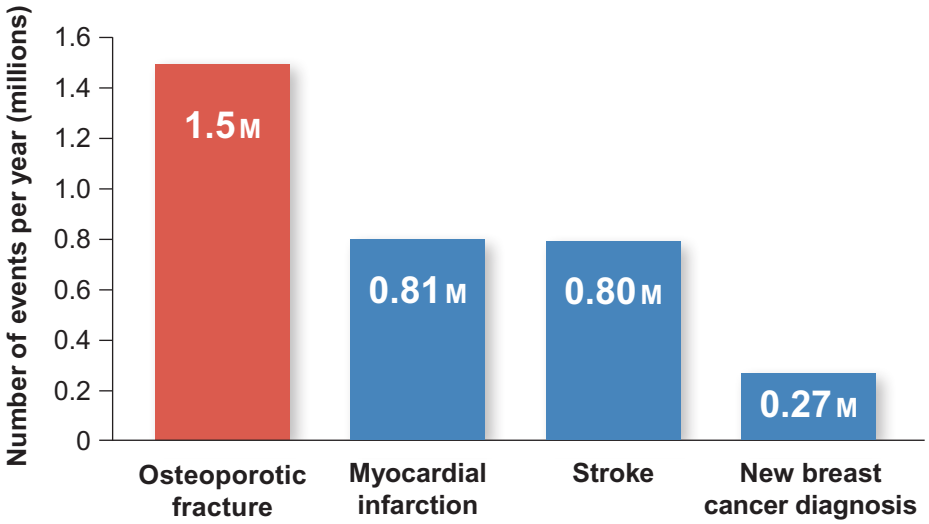
FIGURE 1. Bone density can be safely and easily measured with dual-energy x-ray absorptiometry (DXA).[2,3]

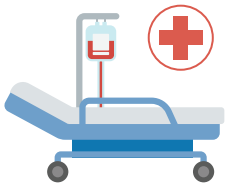


*A T-score compares the patient's bone density to that of a young healthy adult.

Osteoporosis-related fractures are common, and many are preventable.

FIGURE 2. Each year more people in the U.S. have an osteoporotic fracture than a heart attack, stroke, or new breast cancer diagnosis.[4-6]

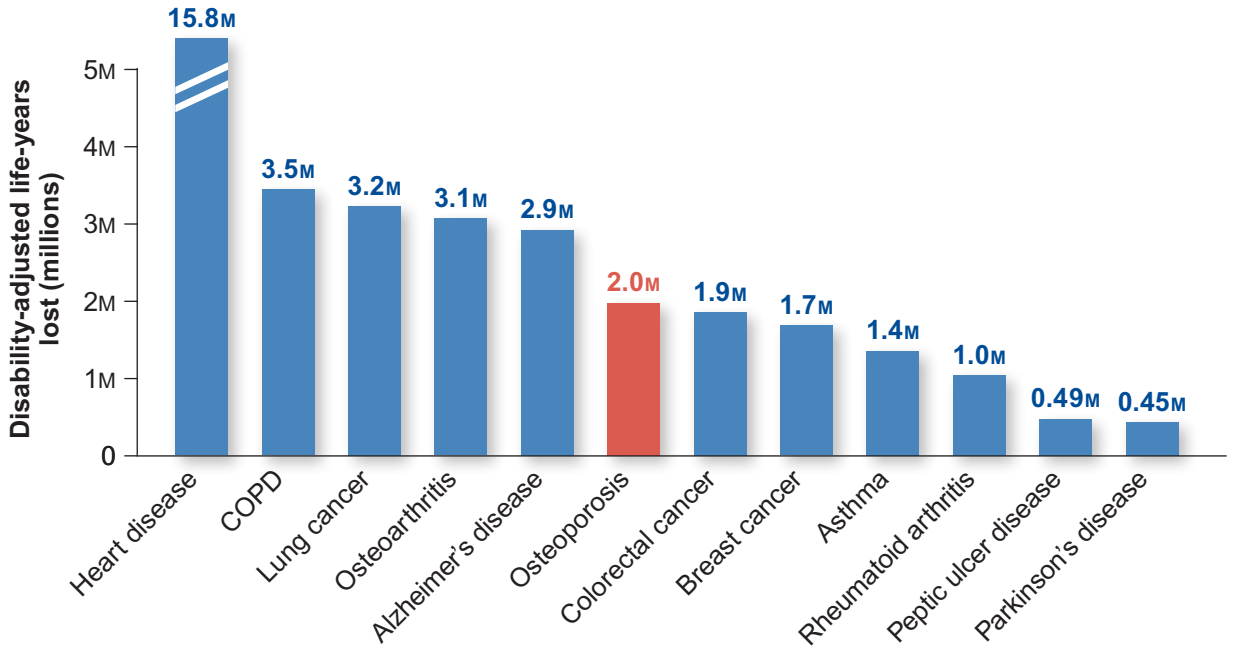




300,000 people in the U.S. are hospitalized annually for a hip fracture.[7]

Morbidity from osteoporosis is high, but effective treatments are underutilized

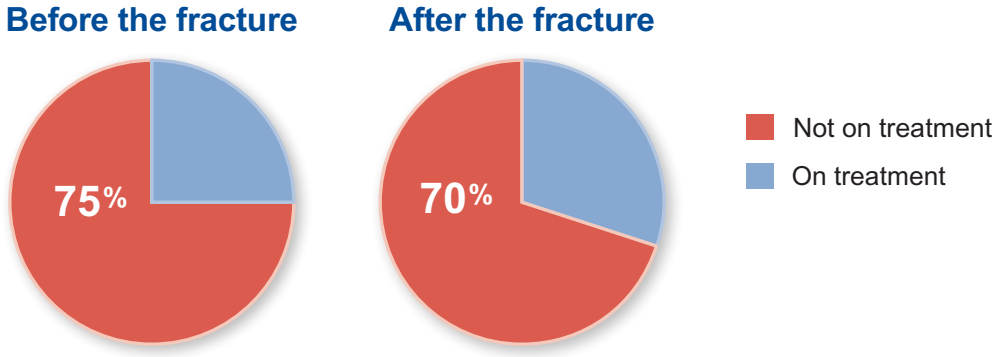
FIGURE 3. Osteoporosis leads to more death and disability than many medical conditions and cancers regularly screened for and treated in primary care.[8]



Black women are *less* likely to be screened for osteoporosis,[9] and they are far *more* likely to suffer death or disability after a fracture.[10]

Medications can help reduce fracture risk and maintain function, but are substantially underused even in the highest-risk patients.

FIGURE 4. Among people with a fragility fracture, few patients were treated before or after the fracture.[11]



Screening for osteoporosis can identify who needs treatment

Decide whether to order a DXA scan based on age and risk factors.

1 DXA is recommended for all older patients:

- all women ≥ 65 years old
- all men ≥ 70 years old

2 Risk-based DXA screening makes sense for some younger adults.

- **Risk factors** for an osteoporotic fracture include:
  - a prior fragility fracture
  - a parent who had a hip fracture
  - glucocorticoid use
  - diabetes
  - smoking
  - rheumatoid arthritis
  - heavy alcohol use (3 or more drinks per day)
  - low body mass index (e.g., less than 20 kg/m^2)

- Evaluate these risk factors in women 51-64 years old and men < 70 years old.
- Screen with a DXA scan if the patient's **10-year fracture risk exceeds 8.4%** by the FRAX score.

Use the FRAX score to determine 10-year fracture risk.

Use the first DXA result to determine the interval for repeat screening.

TABLE 1. On the DXA scan, the initial T-score determines follow up.

T-score	Repeat DXA
0 to -1.5	10-15 years
-1.5 to -2.0	3-5 years
-2.0 to -2.5	1-2 years

Repeat DXA sooner if new clinical risk factors emerge.

Treating osteoporosis can prevent debilitating fractures

FIGURE 5. Comparing the benefits and risks of osteoporosis treatment[12-15]

Fractures averted	NNT for one patient to benefit
Vertebral fractures	17
Non-vertebral fractures	50
Wrist fractures	50
Hip fractures	100

Lower number is better.

Risk of side effects	NNT for one patient to be harmed
Gastrointestinal (GI) side effects	333
Atypical femoral fracture	2,000
Osteonecrosis of the jaw	10,000

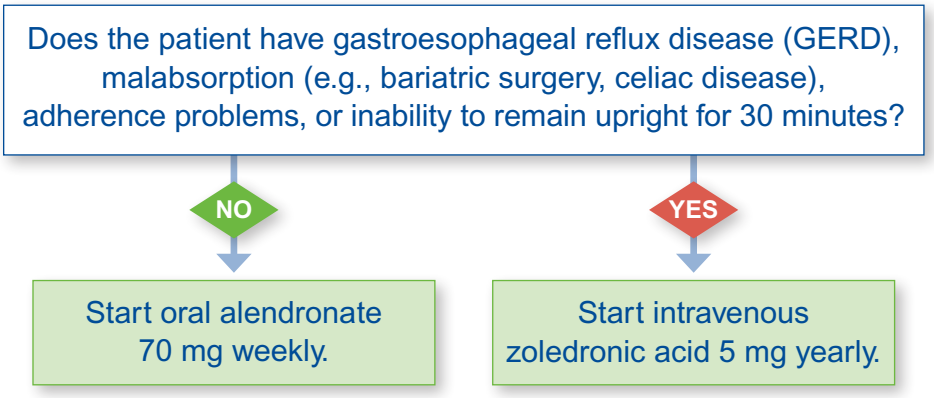
Higher number is better.
NNT = number needed to treat

Prescribe medication for:

- **Patients ≥ 50 with:**[16-18]
  - a history of an osteoporotic fracture, ***or***
  - osteoporosis by bone density (T-score ≤ -2.5 at the spine, total hip, femoral neck, or distal radius), ***or***
  - osteopenia (T-score -1 to -2.5) ***and*** elevated FRAX score predicting a 10-year risk of ≥ 3% for hip fracture or ≥ 20% for major osteoporotic fracture
- **Women ≥ 65 with osteopenia** (T-score -1 to -2.5 at either the spine, total hip, femoral neck, or distal radius)[19]

Bisphosphonates are the first-line therapy.

FIGURE 6. Deciding on the initial bisphosphonate prescription



Patients with creatinine clearance < 35 mL/min should NOT receive a bisphosphonate.

Refer to an endocrine or renal specialist to discuss treatment options.

Assess response and adjust treatment

Repeat DXA 1-2 years after starting treatment.

- Monitoring bone density with DXA leads to improved adherence and lower fracture risk.[20]
- Expect stable or improved bone mineral density after starting treatment.[21]
- **If bone density is decreasing, consider changing treatment:**
  - If taking oral bisphosphonates, change to IV.
  - If taking IV zolendronic acid, consult with an endocrinologist or rheumatologist.
  - If bone density continues to fall, consult with an endocrinologist or rheumatologist.

Adjust the regimen based on side effects, or consult a specialist.

Alendronate (Fosamax, generics): If GI side effects are intolerable, switch to oral risedronate (Actonel, generics) or zoledronic acid IV (Reclast, generics).

Zoledronic acid: If side effects are intolerable, switch to denosumab (Prolia) or consult with an endocrinologist or rheumatologist.

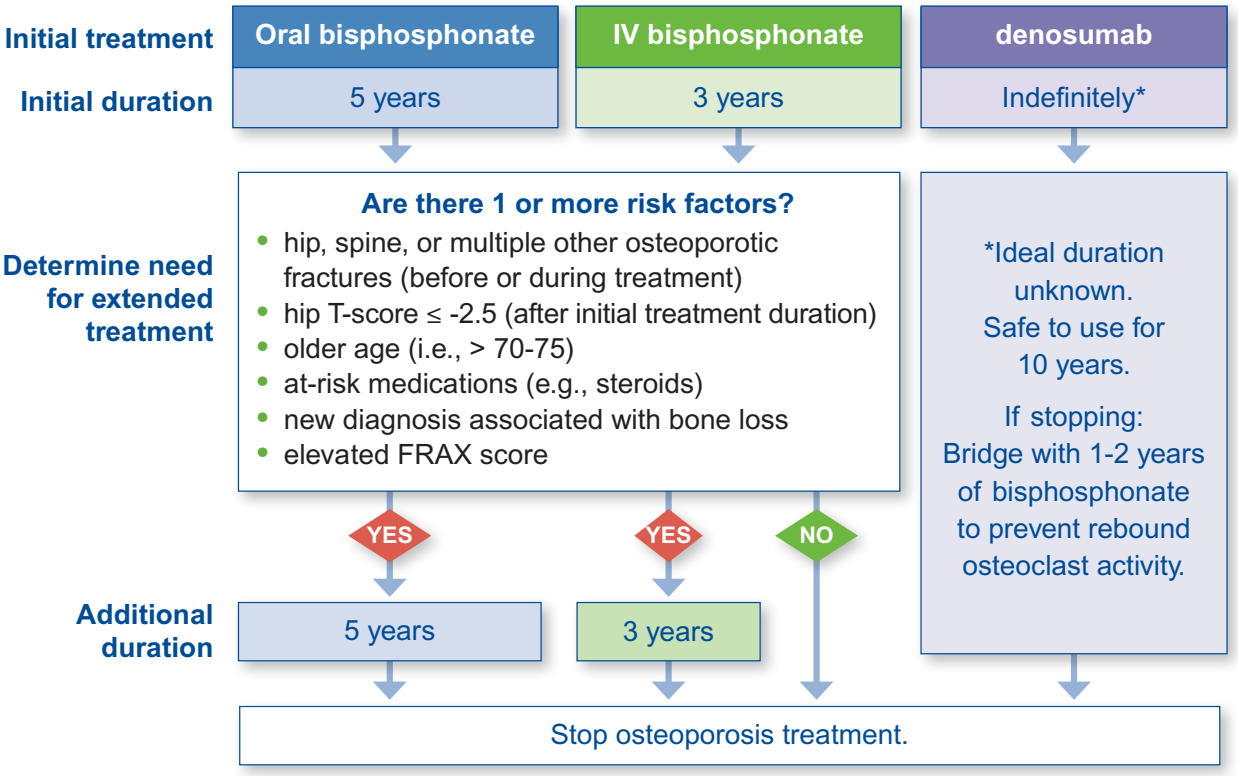
TABLE 2. Specialists use other options for patients with history of fracture or low T-score.

Class	Medication	Route	Dose	Frequency	Comments
Antiresorptive					
Monoclonal antibody	denosumab (Prolia)	SQ	60 mg	6 months	RANKL inhibitor that prevents osteoclast activity; **when stopped, rebound osteoclast activity increases fracture risk.**[22] No adjustment for renal impairment.
Anabolic					
Parathyroid hormone analog	teriparatide (Forteo, generic)	SQ	20 mcg	daily	Therapy limited to 2 years for abaloparatide due to higher osteosarcoma risk in rats (not humans); follow with anti-resorptive therapy to maintain BMD gains.
	abaloparatide (Tymlos)	SQ	80 mcg	daily	
Dual agent					
Sclerostin inhibitor	romosozumab (Evenity)	SQ	210 mg	monthly	Therapy duration of 1 year; switch to bisphosphonate or denosumab at the end of therapy to maintain BMD gains. Black box warning for potential increased cardiovascular risk.

RANKL: receptor activator of nuclear factor kappa beta; SQ: subcutaneous; IV: intravenous
Calcitonin (Miacalcin, generics) and raloxifene (Evista, generics) are options to reduce vertebral fracture.

Treatment is not necessarily lifelong

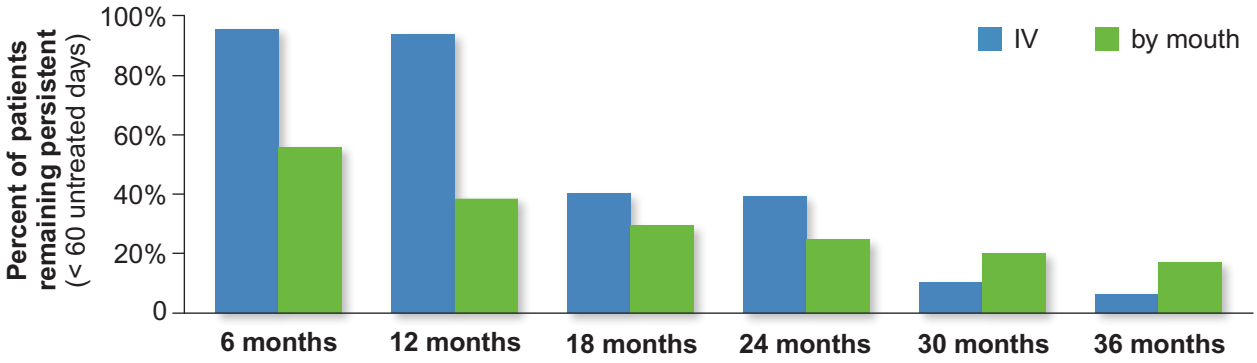
FIGURE 7. Establish treatment duration based on fracture risk.[23-25]



Reassess bone mineral density with a DXA scan ~2 years after stopping therapy. Discuss restarting therapy if the patient develops a new fracture, bone mineral density decreases (or T-score falls below -2.5), or the patient develops new risk factors.[26,27]

Adherence to treatment is challenging regardless of route selected.

FIGURE 8. Few patients remain on treatment for the full course.[28]



Non-prescription options can also improve bone strength

Ensure adequate calcium intake and vitamin D levels.

A 2022 review found that calcium **and** vitamin D co-supplementation reduced fracture rates in patients with known osteoporosis. Supplemental vitamin D and calcium are not beneficial for the general population of older adults.[29,30]

To reduce fracture risk and maintain bone health:

- Ensure that patients take in about **1,200 mg per day of calcium**, preferably from diet.
- Maintain serum **vitamin D level 30-50 ng/mL**,[31] using supplementation if needed (up to 4,000 international units of vitamin D3 per day).

Aim for ≥ 4 servings per day of dietary calcium intake.

1 Serving = 300 mg of calcium, equivalent to:

1 cup milk	1 cup yogurt	1 ounce cheese	Daily intake from non-dairy sources (e.g., bony fish, leafy greens, legumes)
			 

Supplemental calcium is recommended for patients with inadequate dietary intake.

- ≥ 3 servings: no supplement needed
- 1-2 servings: 500-600 mg per day
- 0 servings: 500-600 mg twice a day

Calcium citrate is preferred over calcium carbonate since it more easily absorbed, especially for patients taking a proton pump inhibitor.

Total calcium intake > 2000 mg/day (from diet plus supplements) increases the risk of cardiovascular events.[32]

Maintain activity to strengthen bones and prevent fractures.

Staying active increases bone density and reduces fracture risk.[23,33] A combination of both **resistance and weight-bearing exercises** is best.[34] This can also reduce the risk of falls, another cause of fractures.

Avoid heavy alcohol use.

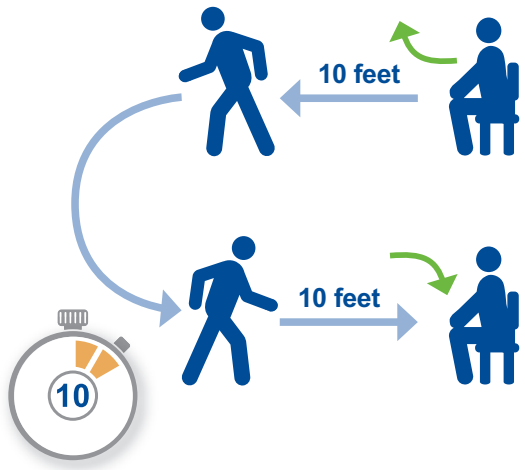
Fracture risk increases with 3 or more drinks per day for women, or 4 or more for men.[35]

Stop smoking.

Smoking reduces bone density and increases the risk of fracture in men and women.[36]

Strategies to reduce fall risk are practical and proven

FIGURE 9. The Timed Up and Go Test (TUG) is an easy office-based assessment that predicts a patient's risk of falling.



Instructions

- Ask the patient to sit in a standard chair.
- Tape a line on the floor 10 feet away.
- Tell the patient to *"Stand up from the chair, walk at your normal pace to the line on the floor, turn, walk back to the chair, and sit down again."*
- Repeat 3 times and average trials 2 and 3.
- Average time > 12 seconds suggests high risk.

In addition, the TUG test may reveal several characteristic gait patterns.

Review common reasons for falling.

TABLE 3. Interventions to reduce fall risk[37]

Risk factor for falls	Treatment options
Poor gait, strength, balance	Refer for physical therapy and/or to an evidence-based exercise or fall prevention program: **www.bit.ly/healthysteps_strength_pa.**
Medications that can increase fall risk (e.g., benzodiazepines, anti-cholinergics, antipsychotics)	Optimize medications by stopping, switching, or reducing dose of these drugs whenever possible.
Home hazards (e.g., throw rugs, uneven floors)	An occupational therapist can evaluate home safety and provide recommendations. This may be reimbursable by Medicare.
Orthostatic hypotension	• Stop, switch, or reduce the dose of contributing medications. • Establish an appropriate blood pressure goal. • Encourage adequate hydration. • Recommend compression stockings.
Visual impairment	• An ophthalmologist can determine whether the patient might benefit from cataract surgery. • Educate about depth perception and single vs. multifocal lenses.
Feet/footwear issues	• Educate about shoe fit, traction, insoles, and heel height. • Refer to a podiatrist.

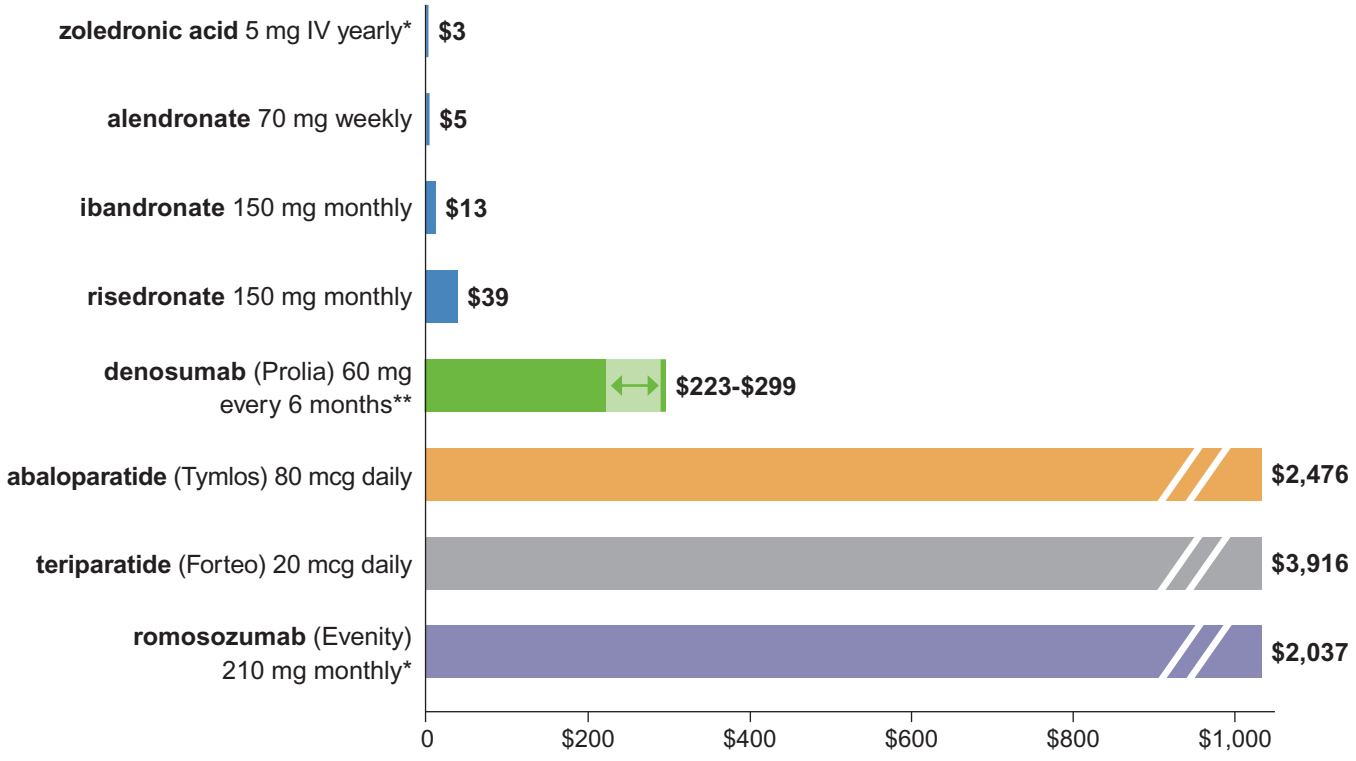
Pennsylvania falls resources

- Pennsylvania Department of Aging: **www.bit.ly/fallsprevention_pa**
- Healthy Steps program
  - Falls prevention: **www.bit.ly/healthysteps_fallsprevention_pa**
  - Strength and balance: **www.bit.ly/healthysteps_strength_pa**
- Falls prevention guide: **www.bit.ly/fallsguide_pa**
- Falls prevention checklist: **www.bit.ly/fallschecklist_pa**

PA Dept of Aging Falls Prevention

Cost of osteoporosis medications

FIGURE 10. The 30-day cost of medications for osteoporosis



Pharmacy prices from goodrx.com, June 2022. Listed doses are based on Defined Daily Doses by the World Health Organization. All doses shown are generics when available, unless otherwise noted. These prices are a guide; patient costs will be subject to copays, rebates, and other incentives.

*From Centers for Medicare and Medicaid Services (CMS) Average Sales Price (ASP), www.cms.gov.

**Price depends on whether the medication is administered by a clinician or obtained at the pharmacy for home injection.

Key points

- Osteoporotic fractures cause **major preventable disability and mortality** in older adults.
- **Screen for osteoporosis with a DXA scan:** all women ≥ 65 years old, men ≥ 70 years old, and patients ≥ 50 years old with risk factors.
- **Bisphosphonates are the first-line treatment** for most patients with osteoporosis and osteopenia.
- Treatment should last at least **5 years for oral bisphosphonates or 3 years for intravenous bisphosphonates,** with longer treatment for those with the highest fracture risk.
- In patients with osteoporosis, **ensure adequate intake of calcium and vitamin D,** recommend exercise, and counsel about the risks of tobacco and alcohol.
- **Encourage exercise, assess and reduce fall risk,** and refer to evidence-based fall prevention programs.

Visit AlosaHealth.org/Osteoporosis
for links to a comprehensive evidence document and other resources.

References:

(1) Wright NC, et al. *J Bone Miner Res.* Nov 2014;29(11):2520-6. **(2)** Siris ES, et al. *Osteoporos Int.* May 2014;25(5):1439-43. **(3)** Rani S, et al. *Biosensors (Basel).* Apr 21 2020;10(4):42. **(4)** Clynes MA, et al. *Br Med Bull.* May 15 2020;133(1):105-117. **(5)** Tsao CW, et al. *Circulation.* Feb 22 2022;145(8):e153-e639. **(6)** American Cancer Society. Breast Cancer Facts & Figures 2019-2020. Atlanta: American Cancer Society, Inc. 2019. **(7)** Swenning T, et al. OTA International. 2020;3(1):e073. **(8)** Johnell O, Kanis JA. *Osteoporos Int.* Dec 2006;17(12):1726-33. **(9)** Miller RG, et al. *J Gen Intern Med.* Sep 2005;20(9):847-51. **(10)** Wright NC, et al. *J Am Geriatr Soc.* Aug 2020;68(8):1803-1810. **(11)** Yusuf AA, et al. *Arch Osteoporos.* Dec 2016;11(1):31. **(12)** Bauer DC, et al. *Arch Intern Med.* 2000;160(4):517-525. **(13)** Wells GA, et al. *Cochrane Database Syst Rev.* Jan 23 2008;(1):Cd001155. **(14)** Shane E, et al. *J Bone Miner Res.* Jan 2014;29(1):1-23. **(15)** Khan AA, et al. *J Bone Miner Res.* Jan 2015;30(1):3-23. **(16)** Camacho PM, et al. *Endocr Pract.* May 2020;26(Suppl 1):1-46. **(17)** Eastell R, et al. *J Clin Endocrinol Metab.* May 1 2019;104(5):1595-1622. **(18)** LeBoff MS, et al. *Osteoporos Int.* Apr 28 2022. **(19)** Reid IR, et al. *J Intern Med.* Aug 2019;286(2):221-229. **(20)** Leslie WD, et al. *J Bone Miner Res.* Oct 2019;34(10):1808-1814. **(21)** Chapurlat RD, et al. *Osteoporos Int.* Jul 2005;16(7):842-8. **(22)** Tsourdi E, et al. *J Clin Endocrinol Metab.* Oct 26 2020. **(23)** Cosman F, et al. *Osteoporos Int.* Oct 2014;25(10):2359-81. **(24)** Ferrari S, et al. *J Clin Endocrinol Metab.* Aug 1 2019;104(8):3450-3461. **(25)** Schwartz AV, et al. *J Bone Miner Res.* May 2010;25(5):976-82. **(26)** Adler RA, et al. *J Bone Miner Res.* Jan 2016;31(1):16-35. **(27)** Bauer DC, et al. *JAMA Intern Med.* Jul 2014;174(7):1126-34. **(28)** Singer AJ, et al. *Osteoporos Int.* Dec 2021;32(12):2473-2484. **(29)** Chakhtoura M, et al. *J Clin Endocrinol Metab.* Feb 17 2022;107(3):882-898. **(30)** LeBoff MS, et al. Supplemental Vitamin D and Incident Fractures in Midlife and Older Adults. *N Engl J Med.* 2022 Jul 28;387(4):299-309. **(31)** Bischoff-Ferrari HA, et al. *N Engl J Med.* Jul 5 2012;367(1):40-9. **(32)** Kopecky SL, et al. *Ann Intern Med.* Dec 20 2016; 165(12):867-868. **(33)** Watson SL, et al. *J Bone Miner Res.* Feb 2018;33(2):211-220. **(34)** Zhao R, et al. *Osteoporos Int.* May 2015; 26(5):1605-18. **(35)** Høidrup S, et al. Copenhagen Centre for Prospective Population Studies. *Am J Epidemiol.* Jun 1 1999; 149(11):993-1001. **(36)** Kanis JA, et al. *Osteoporos Int.* Feb 2005;16(2):155-62. **(37)** Preventing falls in older patients. 2019. Accessed June 10, 2022. https://www.cdc.gov/steadi/pdf/STEADI-PocketGuide-508.pdf.

About this publication

These are general recommendations only; specific clinical decisions should be made by the treating clinician based on an individual patient's clinical condition. More detailed information on this topic is provided in a longer evidence document at AlosaHealth.org.

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