

Osteoporosis Management in Women Who Had a Fracture (OMW)



Objectives

- Define osteoporosis and discuss the impact of low BMD
- Identify risk factors for osteoporosis and review treatment methods
- Describe current efforts and outcomes related to increasing awareness for osteoporosis treatment and prevention
- Discuss the role of healthcare providers in helping prevent osteoporosis and its complications and in improving overall patient health outcomes

NCQA Ratings and HEDIS Measures

- The National Committee for Quality Assurance (NCQA) rates healthcare plans based on the established Healthcare Effectiveness Data and Information Set (HEDIS) Measures.
- The yearly-updated HEDIS measures are based on **endless studies and research** in order **to determine the quality of healthcare services** using **well-defined, measurable outcomes**.
- Medicare Star measure

Osteoporosis

- Bones become porous and fragile from loss of tissue or bone mineral density (BMD)
- BMD peaks early on in adulthood then declines with age, leading to osteoporosis
- “Silent” disease until fractures occur



Impact of Low BMD and Osteoporosis

- **~10 million people** in the US are affected (80% women)
 - **Another 44 million people** have **low BMD**
- Nearly **half of all women** in the US **will experience an osteoporotic fracture** during their lifetime
- Individuals with osteoporosis are significantly more likely to experience low-trauma bone fractures

Preventing Osteoporosis and Fractures

- **Identifying patient risk factors and utilizing BMD screenings** are the most effective methods of **primary prevention of osteoporotic fractures**
- Osteoporosis is commonly treated with medications that help restore the mineral content of bones by facilitating calcium uptake
 - Some of these medications are also used to prevent progression to osteoporosis in patients with low BMD
- Correcting *modifiable risk factors* can *slow down* the degeneration of bones, but adherence is difficult for most patients and *usually not enough without pharmacotherapy*



Risk Factors for Osteoporosis

Non-modifiable – important for assessment

- Advanced age
- Female gender
- Caucasian or Asian race
- Low BMI, of small stature
- Early onset menopause, fewer reproductive years
- Variety of medical conditions

Risk Factors for Osteoporosis

Modifiable

- **Alcohol** abuse
- **Smoking**
- **Frequent falls**
- **Inadequate physical activity**
- **Vitamin D** insufficiency
- Excessive thinness
- High salt intake
- **Low calcium** intake
- Excess vitamin A
- **Immobilization**

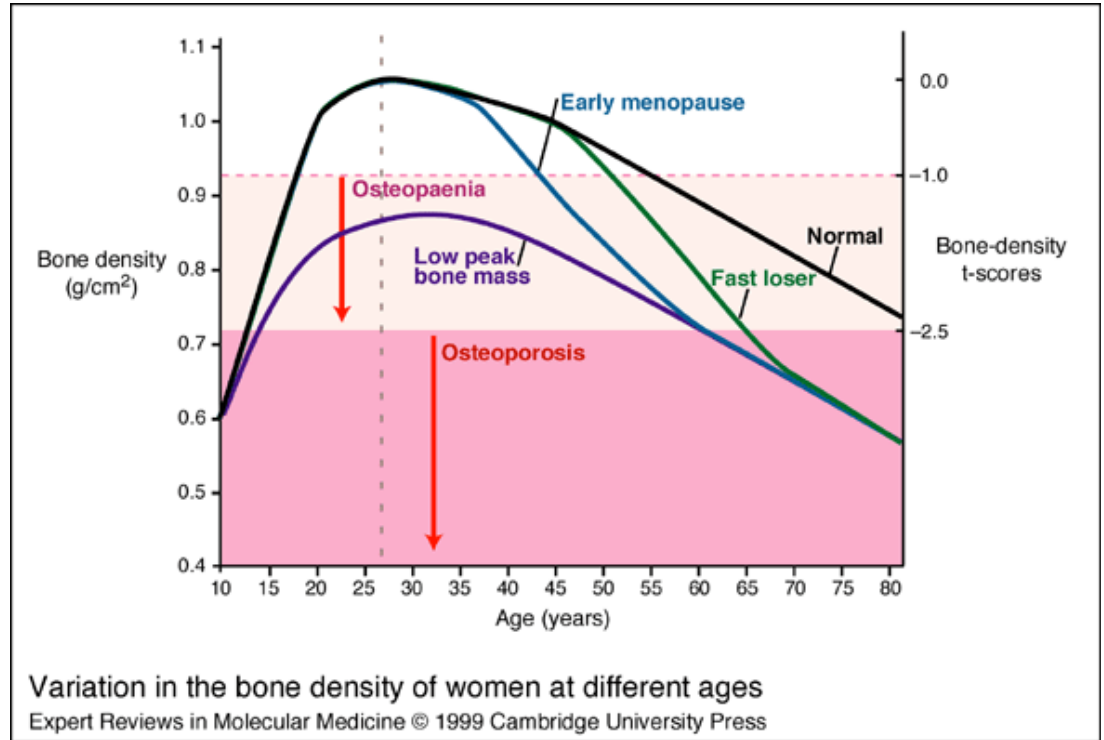
Somewhat Modifiable

- Certain medications
 - Long-term **glucocorticoid** use
 - Cyclosporine, Tacrolimus
 - **PPIs**, Aluminum
 - **Progesterone-only** contraceptives
 - Aromatase inhibitors, MTX, tamoxifen (premenopausal use)
 - Gonadotropin RH, Excess thyroid hormone
 - TPN, Heparin
 - Anticonvulsants, Barbituates
 - SSRIs, Lithium

Menopause and Osteoporosis

HALF of the women in the US will suffer an osteoporotic fracture

18% of postmenopausal women with one or more risk factors for developing osteoporosis actually undergo BMD screenings



Measuring Bone Mineral Density (BMD)

Dual X-ray absorptionometry (DXA)

- **Central DXA** of hip or lumbar spine
 - “**Gold Standard**” for diagnosis
- Peripheral DXA of forearm, wrist or heel

Peripheral ultrasound of heel

- Easy to use, relatively portable
- Ideal for screening at health fairs or in clinics
- Provides T-score
- Calculates risk based on risk factors

Indications for BMD Test

Women \geq 65 and Men \geq 70 – regardless of risk factors

Younger postmenopausal women
Women in menopausal transition
Men 59-69 years old

} with \geq 1 clinical risk factor(s)

Having suffered a fracture after age 50

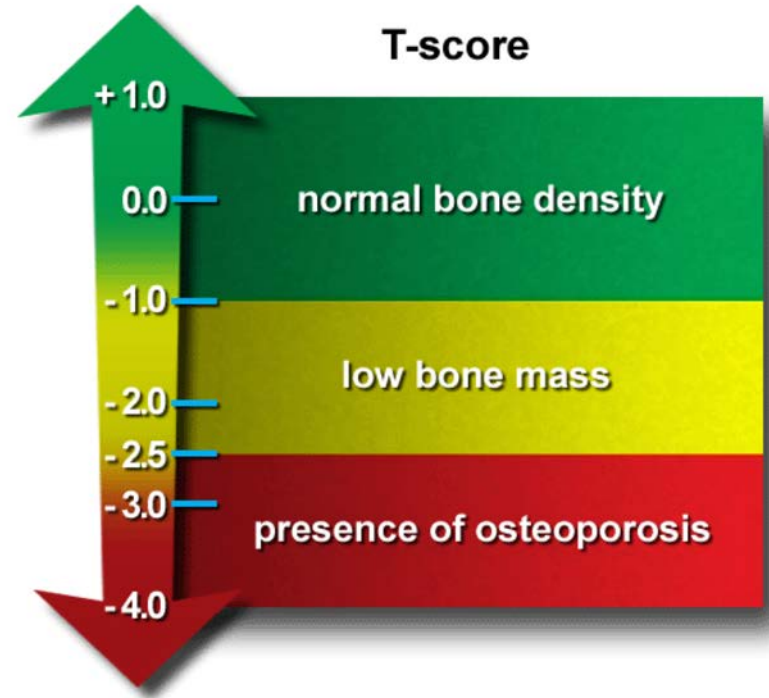
Long-term condition associated with low BMD or bone loss
such as RA

Taking a medication associated with low BMD or bone loss
Glucocorticoid therapy equivalent to \geq 5mg prednisone for \geq 3 months

Bone Mineral Density (BMD)

BMD is measured as a **T-score** value

- T-score of -2.5 or lower indicates presence of osteoporosis.



- Calcium and vitamin D
- Weight-bearing and muscle-strengthening exercise
- Smoking Cessation
- Limiting alcohol intake (≤ 3 alcoholic beverages/day)
- Fall prevention is a key

Calcium & Vitamin D Supplementation

Population	Recommended Daily Intake	
	Calcium	Vitamin D
Females ≤ 50 y/o	1000 mg	400 – 800 IU
Females > 50 y/o	1200 mg	800 – 1000 IU
Males 50-70 y/o	1000 mg	800 – 1000 IU
Males > 70 y/o	1200 mg	800 – 1000 IU

CALCIUM CITRATE VS. CARBONATE?

Citrate = *better tolerated*; can be taken with or without food

Carbonate = *less expensive* but **must** be taken with food

→ **Avoid** CaCO₃ in patients on PPI/antacid therapy

VITAMIN D2 VS. D3?

Vitamin D3 >> D2, both in efficacy and cost for patients

- **Teach and encourage** patients to read nutrition labels on dietary supplements
 - Multivitamins: 20-30% daily calcium requirements
- Take **calcium** in divided doses (max 500mg absorbed at a time)
- Calcium can interact with medications

Diagnosis of Osteoporosis

- Diagnostic criteria vary between organizations, such as those defined by AACE and WHO
- All recommendations** suggest labs to **identify and address possible secondary causes** for osteoporosis, including serum vitamin D levels, calcium, creatinine and TSH

Category	T-score
Normal	-1.0 or above
Low bone mass (osteopenia) ^a	Between -1.0 and -2.5
Osteoporosis	-2.5 or below

^aFracture rates within this category vary widely. The category of “osteopenia” is useful for epidemiology studies and clinical research but is problematic when applied to individual patients and must be combined with clinical information to make treatment decisions.

<ol style="list-style-type: none"> T-score -2.5 or below in the lumbar spine, femoral neck, total, and/or 33% (one-third) radius Low-trauma spine or hip fracture (<i>regardless of BMD</i>) Osteopenia or low bone mass (T-score between -1 and -2.5) with a fragility fracture of proximal humerus, pelvis, or possibly distal forearm Low bone mass or osteopenia and high FRAX[®] fracture probability based on country-specific thresholds

Goals of therapy:

- To prevent fractures by improving bone strength, reducing the risk of falling and injury
- To relieve symptoms of fractures and skeletal deformity
- To maximize physical function



The **National Osteoporosis Foundation (NOF)** recommends pharmacologic treatment for postmenopausal women who meet ONE the following criteria:

1. A hip or spine fracture (either clinical spine fracture or radiographic fracture)
2. A T-score of -2.5 or below at the spine, femoral neck, or total hip
3. A T-score between -1.0 and -2.5 and either one of:
 - a. 10-year risk of 3% or more for hip fracture, or
 - b. 10-year risk of 20% or more for “major” osteoporosis-related fracture

Pharmacologic Treatment Options

- First-line therapy – bisphosphonates
 - Alendronate (Fosamax[®])
 - Ibandronate (Boniva[®])
 - Risedronate (Actonel[®])
 - Zoledronic Acid (Reclast[®])
- Alternative therapies
 - Selective Estrogen Receptor Modulator: Raloxifene (Evista[®])
 - Parathyroid hormone: Teriparatide (Forteo[®])
 - RANKL/RANKL Inhibitor: Denosumab (Prolia[®])
 - Calcitonin – considered last line

Bisphosphonates

Drug	Prevention	Treatment	Clinical Pearls
Alendronate (Fosamax [®] , Fosamax +D [®])	5 mg PO daily 35 mg PO weekly	10 mg PO daily 70 mg PO weekly ^b 70 mg + D ^c	<p>Low PO bioavailability – take on <i>empty</i> stomach, first thing in AM, w/8 oz water; separate from food, meds by >30-60 min^{*^}</p> <p>Side effects: N/V, dyspepsia, GI/esophageal ulceration, musculoskeletal pain To prevent GI ADRs: remain upright, do not lie down >30-60 min after taking PO</p> <p>Serious ADRs: atypical femoral shaft fractures or osteonecrosis of jaw (ONJ) <i>Risk increases w/tx duration of > 5 years</i></p> <p>Consider discontinuing regimen after 5 yrs in low-risk pts</p> <p>Contraindications: esophageal disorders, unable to remain upright, ↑risk of aspiration/dysphagia, renal impairment</p> <p>Alendronate, Risedronate and Zoledronic Acid (<i>ALL but Ibandronate</i>) ↳ Decrease risk of <u>hip, vertebral & non-vertebral fractures</u> <i>Ibandronate</i> → Decreases risk of <u>vertebral fractures</u> (not hip or non-vertebral)</p>
Risedronate (Actonel [®] , Atelvia [®])	5 mg PO daily 35 mg PO weekly 150 mg PO monthly		
Ibandronate (Boniva [®])	2.5 mg PO daily 150 mg PO monthly	2.5 mg PO daily 150 mg PO monthly 3 mg IV q 3 months	
Zoledronic acid (Reclast [®])	5 mg IV q 2 years	5 mg IV once yearly	<p>Ideal for pts requiring bisphosphonate & cannot tolerate PO</p> <p>Pts should be well-hydrated prior to administration, pre-treat w/ APAP</p>

b Fosamax[®] 70 mg available as both a tablet and a unit dose liquid. Alendronate (generic Fosamax) is available

c Fosamax Plus D[®] is tablet containing 70 mg of alendronate + 2,800 IU or 5,600 IU of vit D for weekly administration

d Risedronate 150 mg once monthly tablet is available.

* Except for Atelvia[®] (delayed-release risedronate) which must be taken w/8 oz water **immediately after breakfast**.

^ Minimum 30 min after alendronate or risedronate, and minimum 60 min for *ibandronate*.

Table adapted from AACE/ACE Clinical Practice Guidelines for Diagnosis and Treatment of Postmenopausal Osteoporosis- 2016.

Dosing regimens above are for postmenopausal osteoporosis only. For additional dosing regimens, please refer to drug monographs.

Alternative Agents

Drug	Regimen	Clinical Pearls
Raloxifene (Evista®)	<u>Both Prevention and Treatment:</u> 60 mg PO daily	Decreases risk of vertebral fracture only (not hip or non-vertebral fracture) Common side effects: hot flashes (~1st 6 months of thx), leg cramps Serious ADRs: stroke, VTE – D/C 72 hrs prior to & during prolonged immobilization Contraindications: of child bearing age, history of VTE; Caution: hepatic or renal impt
Estrogen (multiple formulations)	<u>Prevention ONLY:</u> Multiple regimens	No longer recommended for prevention of OP – risks outweigh benefits Use in lowest effective doses for shortest duration to meet treatment goals Pts w/uterus in-tact must take combination therapy progesterone w/estrogen therapy
Denosumab (Prolia®)	<u>Treatment ONLY (high risk*):</u> 60 mg SQ q 6 mos.	Common side effects: back pain, musculoskeletal pain, pancreatitis, hyperlipidemia Serious ADRs: ONJ, Skin or soft tissue infection (SSTI), atypical femoral fractures Contraindications: hypocalcemia, pregnancy
Teriparatide (Forteo®)	<u>Treatment ONLY (high risk*):</u> 20 µg SQ daily	BBW: Osteosarcoma in rats Side effects: N/V, headache, dizziness, leg cramps, pain at inj. site; Rare: ↑ uric acid Contraindications: hx of skeletal malignancy, hypercalcemic disorder, metabolic bone disease NOT TO EXCEED maximum treatment duration of 24 months
Calcitonin (Miacalcin®)	<u>Treatment ONLY:</u> 1x 200 IU nasally daily or 100 IU SQ qod	No longer recommended for use due to increased risk of cancer, thus last-line option For nasal spray, use 1 spray per day in alternating nostrils

* --- **Patients with history of osteoporotic fracture, multiple fracture risk factors, or intolerant to other therapy.**

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Patient Education and Counseling

Patient counseling is key

- Oral bisphosphonates: **must** follow specific directions to maintain efficacy and prevent ADRs
- Forteo[®] & Prolia[®] are specialty drugs, thus typically filled by mail-order pharmacies
→ Patients not likely to receive face-to-face consultation with a pharmacist
- **Counsel patients on proper storage and use**, then ask them to demonstrate it for you
 - Opportunity to make sure they understand how to use medication and what to expect

**THERE ARE
SMARTER WAYS
TO GUARD
AGAINST FALLS.**

Preventing hip fractures from falls is critical for senior home safety. A few common sense precautions can make homes safer and extend independence. A public service message from the American Academy of Orthopaedic Surgeons and the Orthopaedic Trauma Association. For home safety tips, visit orthoinfo.org/falls and ota.org.



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