Osteoporosis in Primary Care

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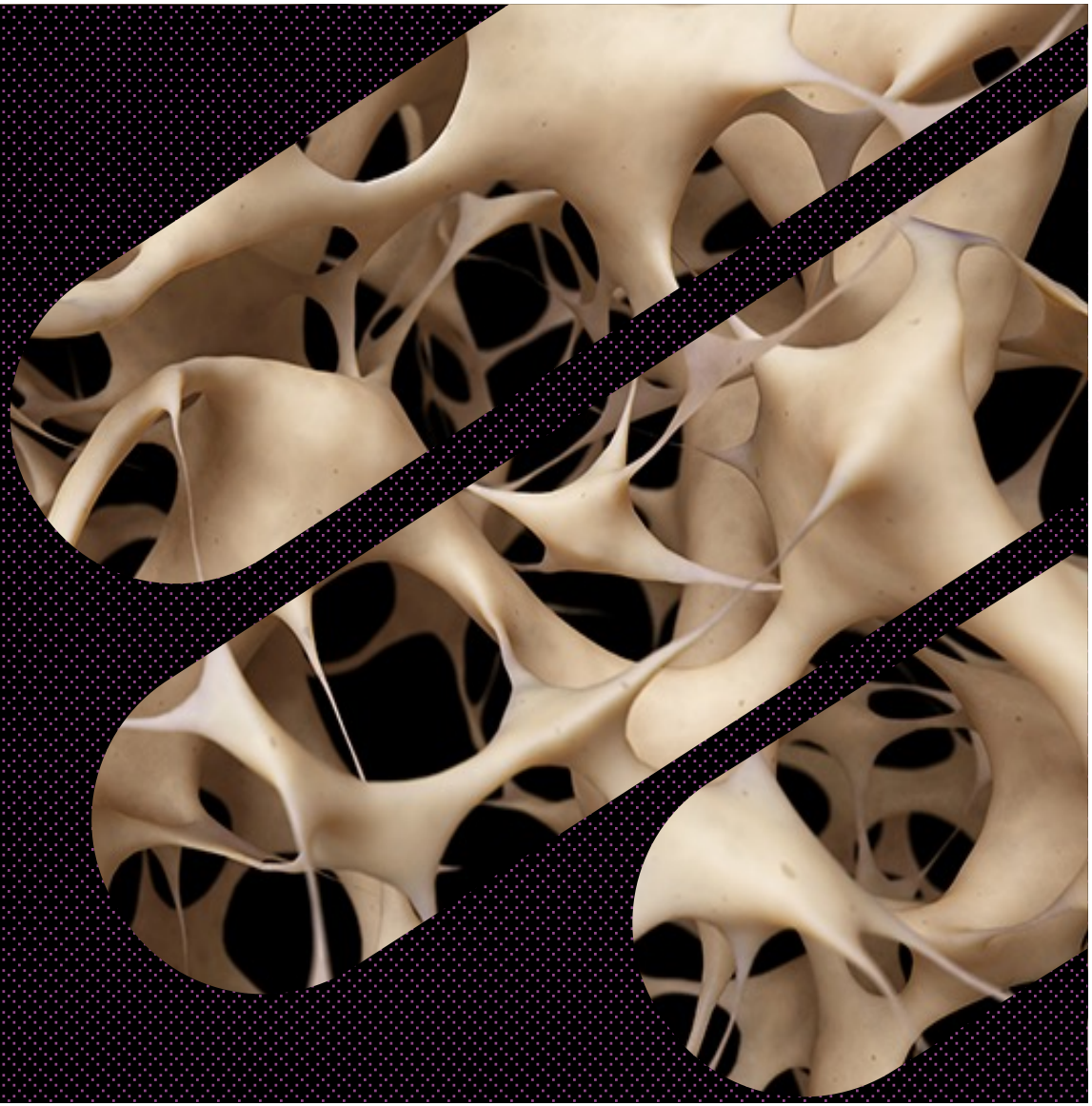
AAPA 2024 - Houston



Introduction

- More than 10 million Americans have osteoporosis
- A chronic, progressive disease characterized by:
  - **Low bone mass**
  - Microarchitecture **deterioration of bone tissue**
  - **Bone fragility** and
  - Consequent **increase in fracture risk**

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Risk Factors

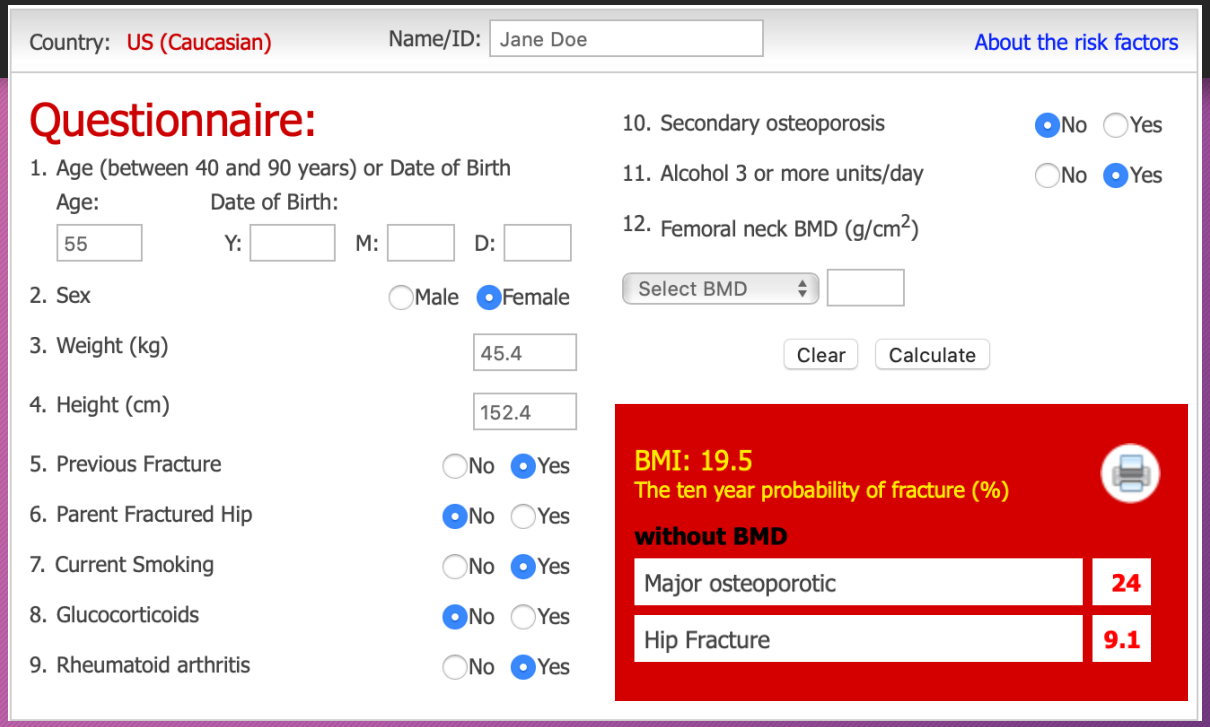
Diagnosis

- What diagnostic study can we use to diagnose osteoporosis?
  - DEXA scan of the lumbar spine and hip

- The World Health Organization (WHO) established commonly accepted definitions of osteoporosis and osteopenia in post-menopausal women and men older than 50 years, by assessing the T-score:

	T-Score
Osteopenia	Between -1.0 and -2.5 SD
Osteoporosis	Greater than -2.5 SD

FRAX Score



Country: US (Caucasian) Name/ID: Jane Doe About the risk factors

Questionnaire:

1. Age (between 40 and 90 years) or Date of Birth
   Age: 55 Date of Birth: Y: M: D:
2. Sex — Male / Female
3. Weight (kg) 45.4
4. Height (cm) 152.4
5. Previous Fracture — No / Yes
6. Parent Fractured Hip — No / Yes
7. Current Smoking — No / Yes
8. Glucocorticoids — No / Yes
9. Rheumatoid arthritis — No / Yes
10. Secondary osteoporosis — No / Yes
11. Alcohol 3 or more units/day — No / Yes
12. Femoral neck BMD (g/cm^2)

Select BMD

Clear Calculate

BMI: 19.5
The ten year probability of fracture (%)

without BMD

Major osteoporotic	24
Hip Fracture	9.1

If results reveal an **increased major osteoporotic fracture risk of 20%** or a **risk of hip fracture of at least 3% in a patient with osteopenia**, treatment is indicated

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Diagnosis

- But what about those patient's who are men younger than 50 years, children, or premenopausal women?
  - Assess the Z-score

- A Z-score of _____ is consistent with osteoporosis
  - Greater than -2.0 STD

So, what is the difference between a T-score and Z-score?

Screening

The U.S. Preventive Services Task Force (USPSTF) recommends screening **all women 65 years and older** with DEXA of the hip and lumbar spine

The USPSTF also advises screening postmenopausal women **younger than 65 years** who are at increased risk or **those over 50 years with…**

Although guidelines for rescreening women with **normal initial screening results** are lacking, recent evidence suggests that intervals of at least ***four to five years*** appear safe

Next Slide…

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Screening

- Premenopausal Women (≥ **50 years**)
  - Osteoporosis screening tool (OST)
    - The Osteoporosis Screening Tool (OST) calculates risk based on weight and age

- OST formula: (weight [kg] - age) x 0.2
  - **<u>In patients ≥ 50 years, if score is <2</u>**
    - **Get DEXA**

- **(49 kg – 62 years old) x 0.2 =**
  - **-2.6**

Body Weight lbs.	AGE (years) 45–49	50–54	55–59	60–64	65–69	70–74	75–79	80–84	85–89	90–94	95–99	Body Weight lbs.
66–75	–3	–4	–5	–6	–7	–8	–9	–10	–11	–12	–13	66–75
76–87	–2	–3	–4	–5	–6	–7	–8	–9	–10	–11	–12	76–87
88–98	–1	–2	–3	–4	–5	–6	–7	–8	–9	–10	–11	88–98
99–109	0	–1	–2	–3	–4	–5	–6	–7	–8	–9	–10	99–109
110–120	1	0	–1	–2	–3	–4	–5	–6	–7	–8	–9	110–120
121–131	2	1	0	–1	–2	–3	–4	–5	–6	–7	–8	121–131
132–142	3	2	1	0	–1	–2	–3	–4	–5	–6	–7	132–142
143–153	4	3	2	1	0	–1	–2	–3	–4	–5	–6	143–153
154–164	5	4	3	2	1	0	–1	–2	–3	–4	–5	154–164
165–175	6	5	4	3	2	1	0	–1	–2	–3	–4	165–175
176–186	7	6	5	4	3	2	1	0	–1	–2	–3	176–186
187–197	8	7	6	5	4	3	2	1	0	–1	–2	187–197
198–208	9	8	7	6	5	4	3	2	1	0	–1	198–208
209–219	10	9	8	7	6	5	4	3	2	1	0	209–219
220–230	11	10	9	8	7	6	5	4	3	2	1	220–230

Screening

What about screening for men?

- The National Osteoporosis Foundation also recommends **screening all men 70 years and older**, based on the assumption that this group has a similar osteoporotic fracture risk and treatment effectiveness as 65-year-old white women
- However, the **USPSTF does not endorse this recommendation; and notes that all average risk men should not be screened.**

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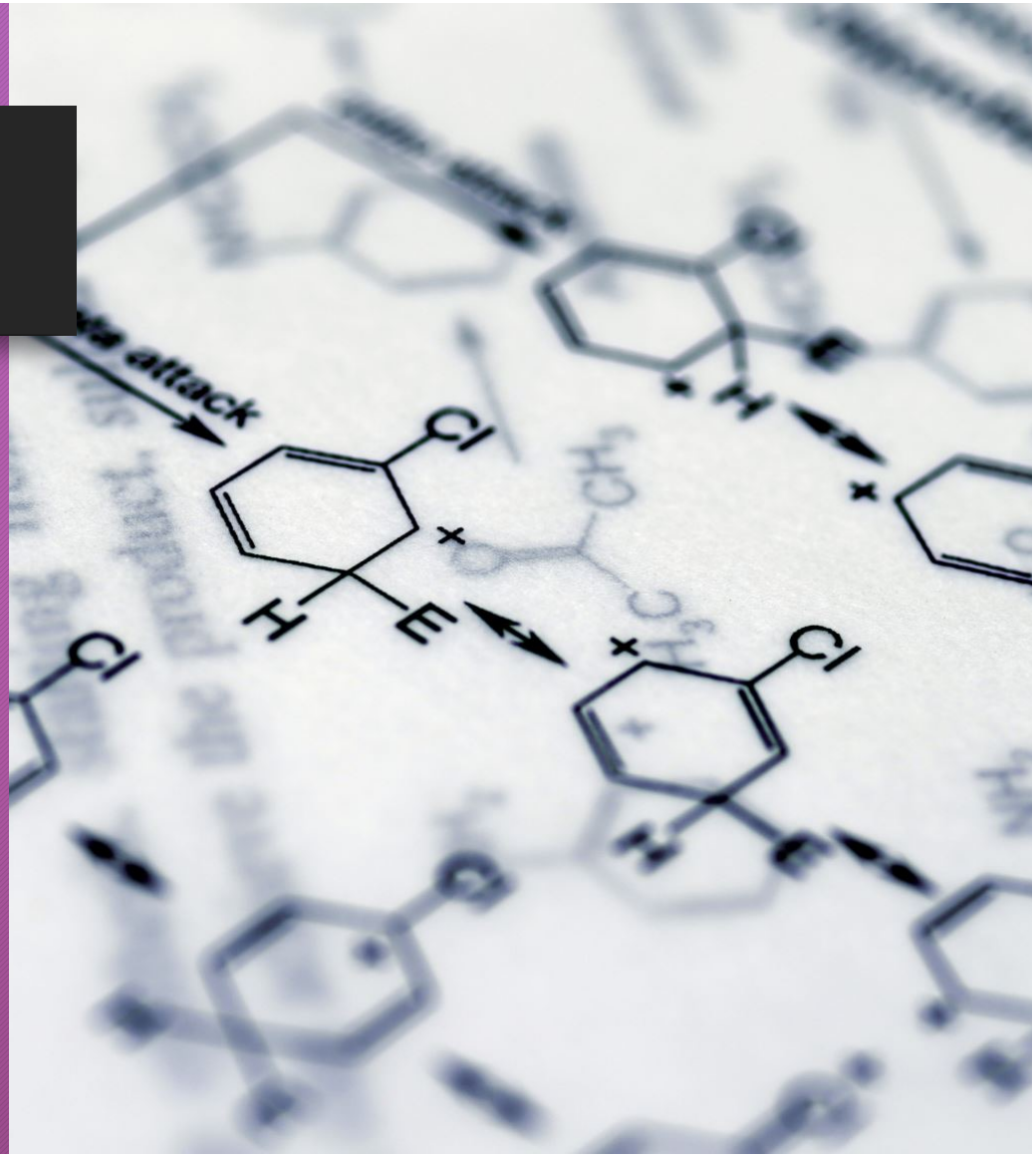
Primary vs. Secondary Osteoporosis

- Primary osteoporosis is related to aging and loss of gonadal function
- Secondary osteoporosis is caused by other health conditions
- Up to 30% of osteoporosis cases in postmenopausal women are estimated to be from a secondary cause
- The estimate climbs to greater than 50% in **men**, **premenopausal women**, and **perimenopausal women** if vitamin D deficiency is included as a secondary cause

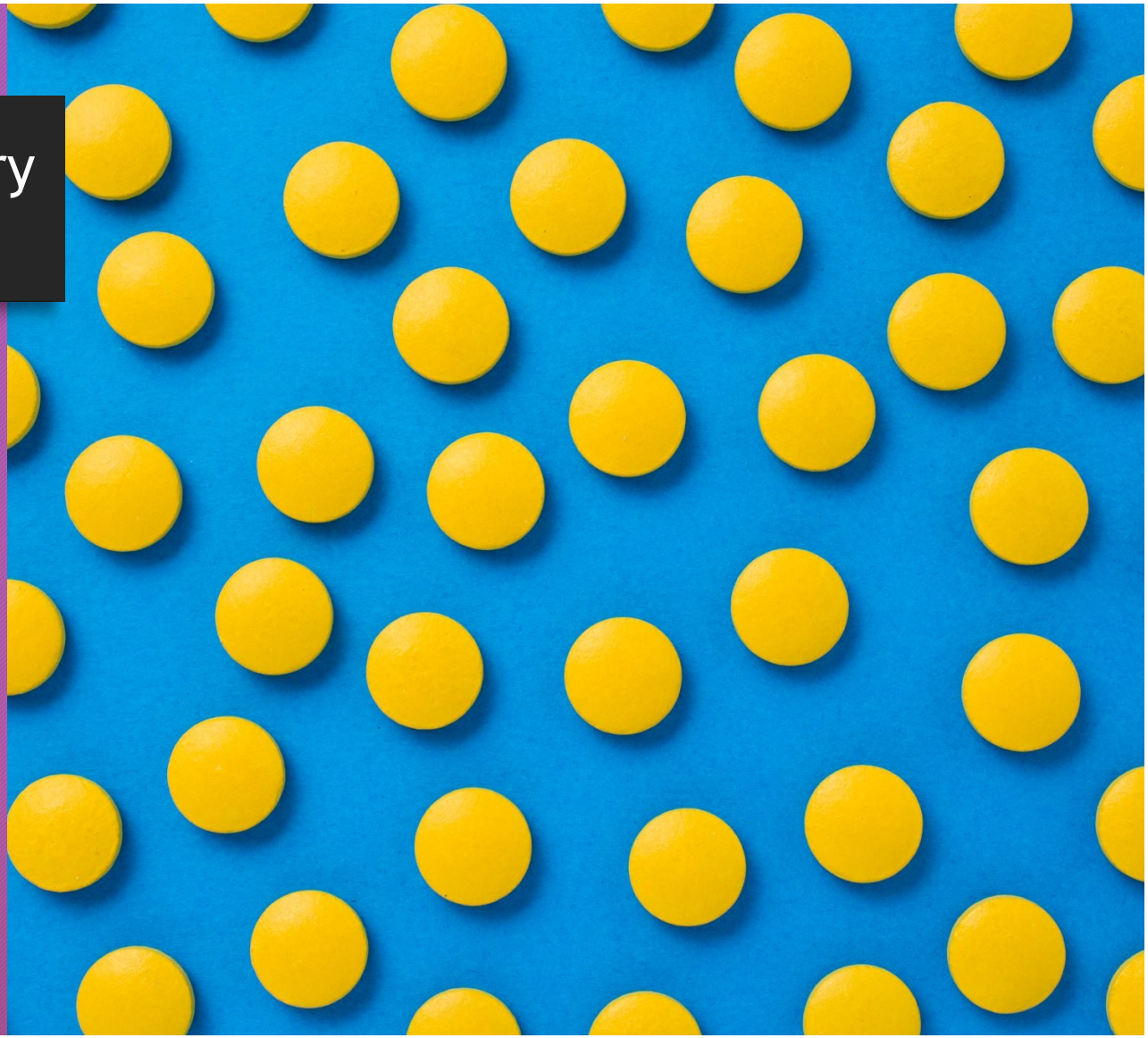


Medical Conditions and Secondary Osteoporosis

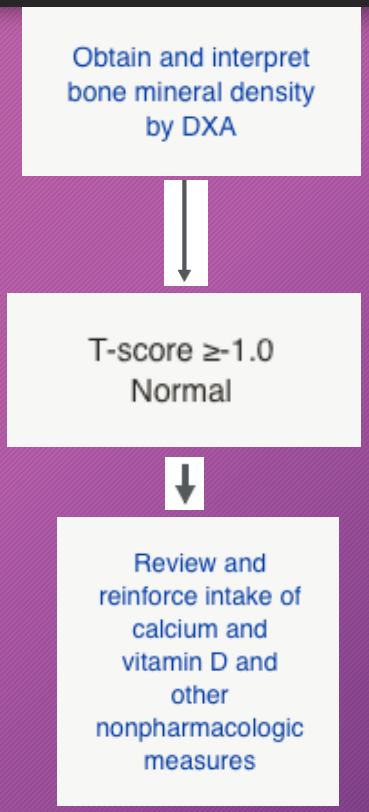
- CNS Disorders
  - Epilepsy, MS, PD, spinal cord injury, CVA
- COPD
- Endocrine Disorders
  - Addison's, athletic amenorrhea, Cushing's hemochromatosis, hyperparathyroidism, hyperthyroidism, hypogonadism, T1DM)
- GI Disorders
  - Celiac disease, malabsorption, IBD, gastric bypass, PBC
- HIV and AIDS
- Liver Disease
- Alcoholism, anorexia, bulimia, vitamin D deficiency, vitamin A excess
- Renal failure
- RA and SLE

Medications and Secondary Osteoporosis

- Anticonvulsants
  - Phenobarbital, phenytoin
- Chemotherapy
- Cyclosporine
- Depo-Provera
- Steroids
- Gonadotropin-releasing hormone agonists
- Heparin
- Methotrexate
- PPI
- SSRI
- Tacrolimus
- Tamoxifen
- TZDs
- Levothyroxine if too high of a dose



Treatment


Obtain and interpret bone mineral density by DXA
T-score ≥-1.0 Normal
Review and reinforce intake of calcium and vitamin D and other nonpharmacologic measures

Nonpharmacologic Treatment

- Fall prevention is a priority for patients with osteoporosis because falls are more closely associated with fracture risk than is BMD
- The USPSTF recommends weight bearing and balance training and vitamin D supplementation
- Smoking cessation
  - Smoking has been shown to decrease BMD at all skeletal sites
- Alcohol reduction
  - Decreasing alcohol (<4 beverages daily for men, and <2 beverages daily for women)
- Caffeine reduction
  - More than 2.5 units of caffeine daily (1 unit = one cup of coffee or two cups of tea) may increase fracture risk
- Increased protein intake
  - Necessary for optimal bone health, but the proper amount or source (plant vs. animal) remains controversial
- A balanced diet consisting of vitamin D, calcium, protein, vegetables, and fruits is recommended

Recommended Calcium Intake

Women	
50 years and younger	1,000 mg daily
51 years and older	1,200 mg daily

Men	
70 years and younger	1,000 mg daily
71 years and older	1,200 mg daily

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Recommended Vitamin D Intake

Vitamin D

- Obtained from foods, supplements or sunlight
- Foods include: fatty fish like salmon, tuna and mackerel. Vit D also found in milk, orange juice, fortified cereals and soymilk

Women and men	
< 50 years	600 international units daily
≥ 50 years	600-1000 IU daily

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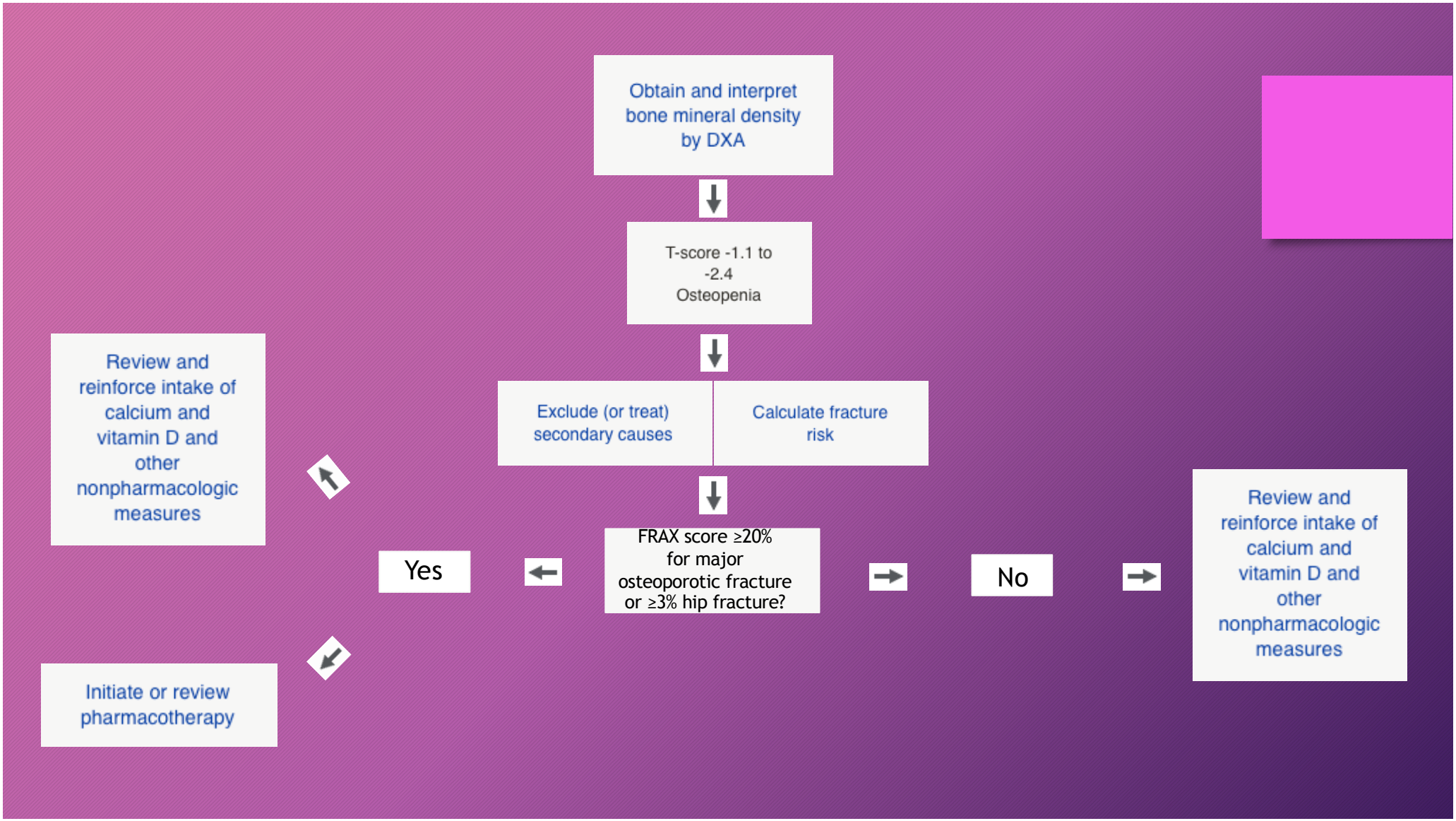
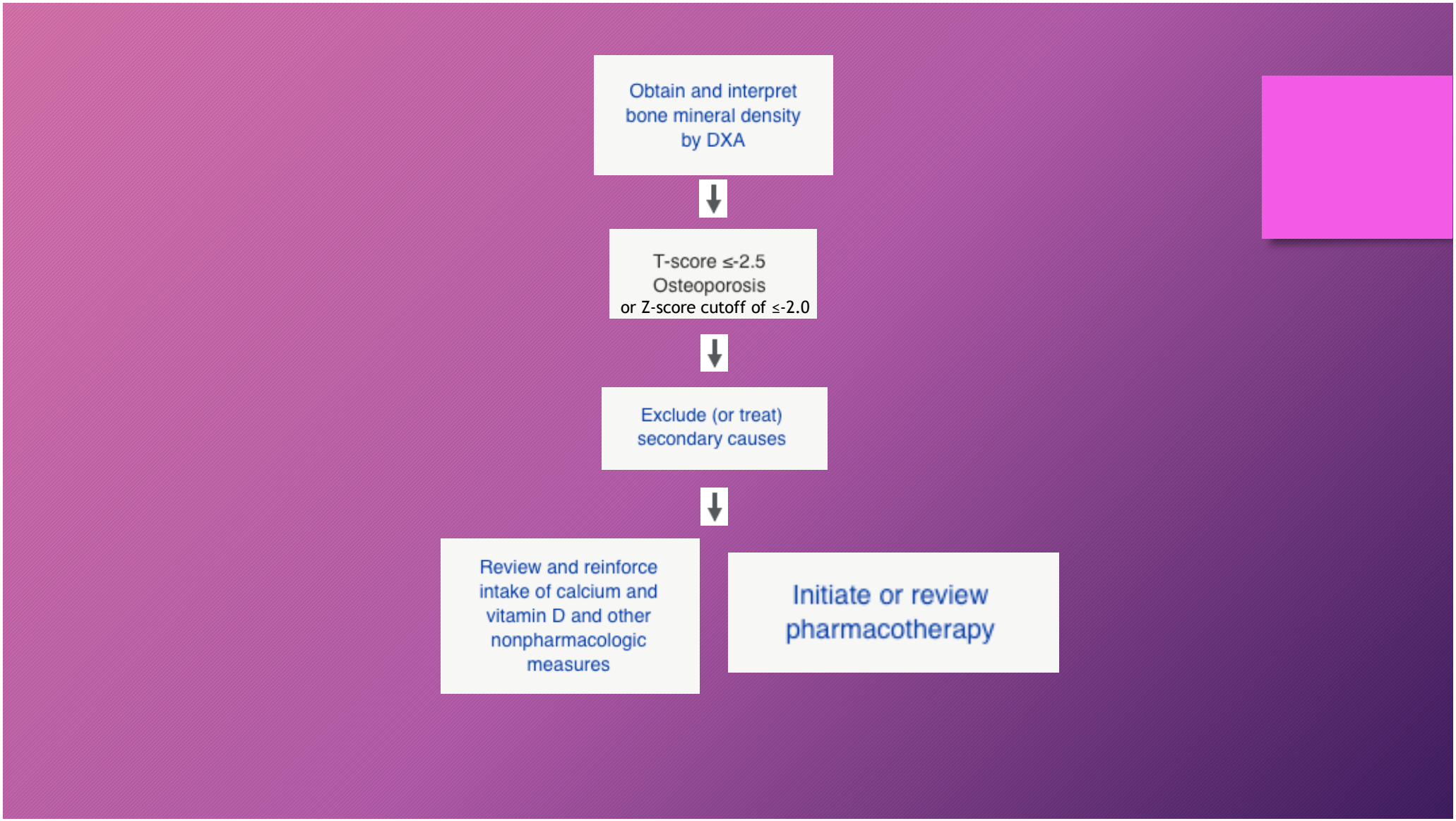

Obtain and interpret bone mineral density by DXA
T-score -1.1 to -2.4 Osteopenia
Exclude (or treat) secondary causes
Calculate fracture risk
FRAX score ≥20% for major osteoporotic fracture or ≥3% hip fracture?
Yes
No
Review and reinforce intake of calcium and vitamin D and other nonpharmacologic measures
Initiate or review pharmacotherapy
Review and reinforce intake of calcium and vitamin D and other nonpharmacologic measures


Obtain and interpret bone mineral density by DXA
T-score ≤-2.5 Osteoporosis or Z-score cutoff of ≤-2.0
Exclude (or treat) secondary causes
Review and reinforce intake of calcium and vitamin D and other nonpharmacologic measures
Initiate or review pharmacotherapy

Treatment

The National Osteoporosis Foundation recommends treatment of postmenopausal women and men with:

- Osteopenia (T-score –1 to –2.5) and a 10-year FRAX score hip fracture ≥3% or any major fracture ≥20%
- A T-score of –2.5 or less or Z-score cutoff of ≤-2.0
- A personal history of hip or vertebral fracture

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Pharmacologic Treatment - Bisphosphonates

- Oral bisphosphonates inhibit osteoclastic activity and are antiresorptive agents and are considered first-line pharmacologic therapy
- Randomized clinical trials demonstrate a reduction of vertebral, hip, and non-vertebral fractures with **alendronate** (Fosamax) and **risedronate** (Actonel)
- Oral bisphosphonates should be taken only with water and a wait of at least 30 minutes before reclining or ingesting other medication or food
  - This decreases upper gastrointestinal adverse effects and allows for appropriate absorption

Bisphosphonates

Route	Contraindications	Adverse effects	Dosing	Precautions	Cost
Oral	eGFR <35* mL/min; uncontrolled GERD, dysphagia, esophageal disease	Esophagitis, musculoskeletal symptoms	Weekly — alendronate (Fosamax, Binosto) or risedronate (Actonel, Atelvia) — or monthly — ibandronate (Boniva)** or risedronate (Actonel, Atelvia)	Take on an empty stomach without other medications, supplements, or food; do not lie down for at least 30 minutes afterward	Low

Pharmacologic Treatment - Bisphosphonates

- The intravenous bisphosphonates approved by the U.S. Food and Drug Administration for the treatment of postmenopausal osteoporosis are:
  - Zoledronic acid (Reclast), 5 mg yearly (shown to decrease vertebral, hip, and non-vertebral fractures)
  - Ibandronate, 3 mg every three months (helps to increase BMD, but only decreases vertebral fractures)

- Although these medications are expensive, they are useful for high-risk patients who are unable to tolerate or adhere to oral therapy
  - Patients with uncontrolled GERD, dysphagia, poor absorption

Bisphosphonates

Route	Contraindications	Adverse effects	Dosing	Precautions	Cost
IV	eGFR ≤35 mL/min	Postinfusion fever and myalgia (24 to 72 hours in duration), transient hypocalcemia, musculoskeletal symptoms	Annually — zoledronic (Reclast); nurse administered	Acetaminophen 500 mg every 6 hours for 3 days beginning 4 hours post-infusion	Moderate

But What About Side Effects?!?

- Osteonecrosis of the jaw
  - The risk is estimated at **<1 case per 10,000 patient-years of oral bisphosphonates** treatment for osteoporosis without additional risk factors
  - Although less well-delineated, the risk associated with denosumab therapy is similarly low
  - Even so, prudence dictates promoting prophylactic dental examination and dental hygiene before initiation of an antiresorptive drug
  - Although it has not been demonstrated to influence the risk of osteonecrosis, a common approach is to stop bisphosphonate therapy 3 months prior to and for 3 months after elective invasive dental procedure

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But What About Side Effects?!?

- Atypical Femur Fractures
  - Incidence is low ranging from 2 to 100 per 100,000 patient-years of antiresorptive drug treatment
  - Risk is low compared to number of osteoporotic fractures prevented
  - Risk may increase with increasing duration of treatment (e.g. >5 years)
  - Any patient taking antiresorptive drugs who has new groin or thigh pain should undergo bilateral femur radiographs
    - If abnormalities are seen, orthopedic evaluation is indicated

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Pharmacologic Treatment - Bisphosphonates

- The optimal length of oral bisphosphonate therapy is unknown
- One study found that women who take alendronate for five years followed by five years of placebo have **no increased incidence of nonvertebral or hip fractures** compared with women who take alendronate for 10 years
  - There is, however, an increase in vertebral fractures
- Osteonecrosis of the jaw and atypical femoral fractures are rare complications of bisphosphonate therapy that are **associated with longer duration of use**
- Clinicians should consider discontinuing bisphosphonate therapy **after five years** in women without a personal history of vertebral fractures

Pharmacologic Treatment - Denosumab

Denosumab is a human monoclonal antibody that inhibits the formation and activity of osteoclasts by blocking receptor activator of nuclear factor kappa B ligand

In a dose of 60 mg given subcutaneously **every six months**

Denosumab has been shown to **decrease hip, vertebral, and nonvertebral fractures** compared with low doses of calcium and vitamin D

It appears to be a reasonable alternative for persons whose condition does not improve with bisphosphonates

The optimal duration of treatment with denosumab is unclear; available data support its continued efficacy for 10 years

The effects of denosumab on BMD and bone turnover are reversible when the drug is stopped.

Stopping the drug after 24 months of treatment resulted in increased bone turnover markers within 3 months and a decline in BMD to pretreatment values within 2 years

Renal insufficiency is a listed caution, but denosumab appears to be safe for patients with chronic kidney disease **stages 1 to 3**

Summary - Denosumab

- May be preferred in a
  - Patient with an eGFR <35 mL/min
  - Patient with postmenopausal osteoporosis with a very high risk of fracture
  - Patient failing bisphosphonate therapy

- Denosumab must be administered every 6 months for 5 to 10 years.
- Discontinuation or disruption will result in decline in bone density and may increase the risk of spinal compression fractures.
  - Bisphosphonates must be initiated 6 months after last treatment with denosumab

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Pharmacologic Treatment - Raloxifene

Raloxifene, a selective estrogen receptor modulator, is approved for treating **postmenopausal osteoporosis**, and is effective at reducing vertebral fractures only

Raloxifene is commonly associated with **increased vasomotor symptoms**, and is associated with an increased risk of venous thromboembolism and a decreased risk of invasive breast cancer

The best candidates for raloxifene are:

Postmenopausal women with osteoporosis who are unable to tolerate bisphosphonates	**Have no vasomotor symptoms or history of venous thromboembolism**	**Have a high breast cancer risk**

Bazedoxifene is a selective estrogen receptor modulator more recently approved for use in the United States for the ***prevention (not treatment)*** of osteoporosis as part of a combination therapy with conjugated estrogen (Duavee)

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Summary - Raloxifene

- Can be considered for women who are not able to willing to take bisphosphonates, denosumab, or teriparatide; have osteoporosis but have not had osteoporotic fractures
- Might be preferred when both osteoporosis treatment and breast cancer prevention are desired since raloxifene is indicated for primary prevention of breast cancer in select patients
- Should not be used in women with an increased risk of thromboembolic complications

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Summary – Estrogens/Bazedoxifene (Duavee)

- Has been approved for **prevention** of osteoporosis in women
- Likely has some effect on reducing risk of fracture in women with osteoporosis
- Is not considered sufficient therapy for women who have experienced an osteoporotic fracture or are at high risk for fractures
- Can be considered for women who choose to take estradiol for other reasons, especially in patients reluctant to use approved osteoporosis medications

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Pharmacologic Treatment - Calcitonin

Calcitonin nasal spray is an antiresorptive agent approved for the treatment of **postmenopausal osteoporosis**

It has been shown to decrease the occurrence of vertebral compression fractures only

Calcitonin has modest analgesic properties in the setting of acute vertebral compression fracture

There have also been reports of increased cancer rates associated with use of calcitonin

Pharmacologic Treatment – Teriparatide and Abaloparatide

Teriparatide and Abaloparatide are a recombinant human parathyroid hormone with bone anabolic activity

In a dosage of 20 mcg per day given subcutaneously for **up to two years**, teriparatide decreases vertebral and nonvertebral fractures; **NOT hip fractures**

Teriparatide is approved for the treatment of:

- Postmenopausal women with severe bone loss
- Men with osteoporosis who have high risk of fracture
- Individuals whose condition has not improved with bisphosphonate therapy

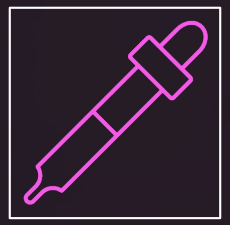
One study suggests that it is advisable to follow teriparatide therapy with bisphosphonate therapy to maintain BMD gains

BMD decreases after the drug is stopped, but retreatment after a drug-free period has been shown to produce small gains in BMD

Switching from teriparatide or a combination of teriparatide and denosumab to denosumab monotherapy results in further increases in BMD

	Contraindications	Adverse effects	Dosing	Cost
Abaloparatide (Tymlos), teriparatide (Forteo) (subcutaneous)	History of radiation therapy or hyperparathyroidism, primary skeletal malignancy	Mild hypercalcemia	Daily self-injection for 2 years	High

Pharmacologic Treatment – Romosozumab (Evenity)



Romosozumab *(Evenity)* is a monoclonal antibody that binds to and inhibits sclerostin, increasing bone formation and decreasing bone resorption

It is FDA-approved for once-monthly subcutaneous treatment of osteoporosis for **up to one year** in postmenopausal women who are at high risk for fracture or have not responded to or could not tolerate other drugs for this indication

Arthralgia and headache were the most common adverse effects reported with use of romosozumab in clinical trials

Pharmacologic Treatment – Romosozumab (Evenity)

- Three cases of atypical femoral fractures and three cases of jaw osteonecrosis were reported in patients who received romosozumab
- Serious adverse cardiovascular events occurred more frequently with romosozumab than with alendronate; in a second trial the rate was not higher with romosozumab than with placebo
- Romosozumab should not be used in patients who had a myocardial infarction or stroke within the previous year
- Neutralizing antibodies to romosozumab have developed; whether they reduce the efficacy of the drug is unknown

Summary - Abaloparatide (Tymlos), teriparatide (Forteo), Romosozumab (Evenity)

- These agents may be preferred in specific patients who:
  - Have declining bone mineral density or recurrent fractures despite bisphosphonate therapy
  - Have glucocorticoid-induced osteoporosis (teriparatide)
  - Have very low bone density
  - Have sustained multiple fractures
  - Are younger than age 55 years, have very low bone density, and have not sustained fractures
  - Are intolerant to other osteoporosis medications

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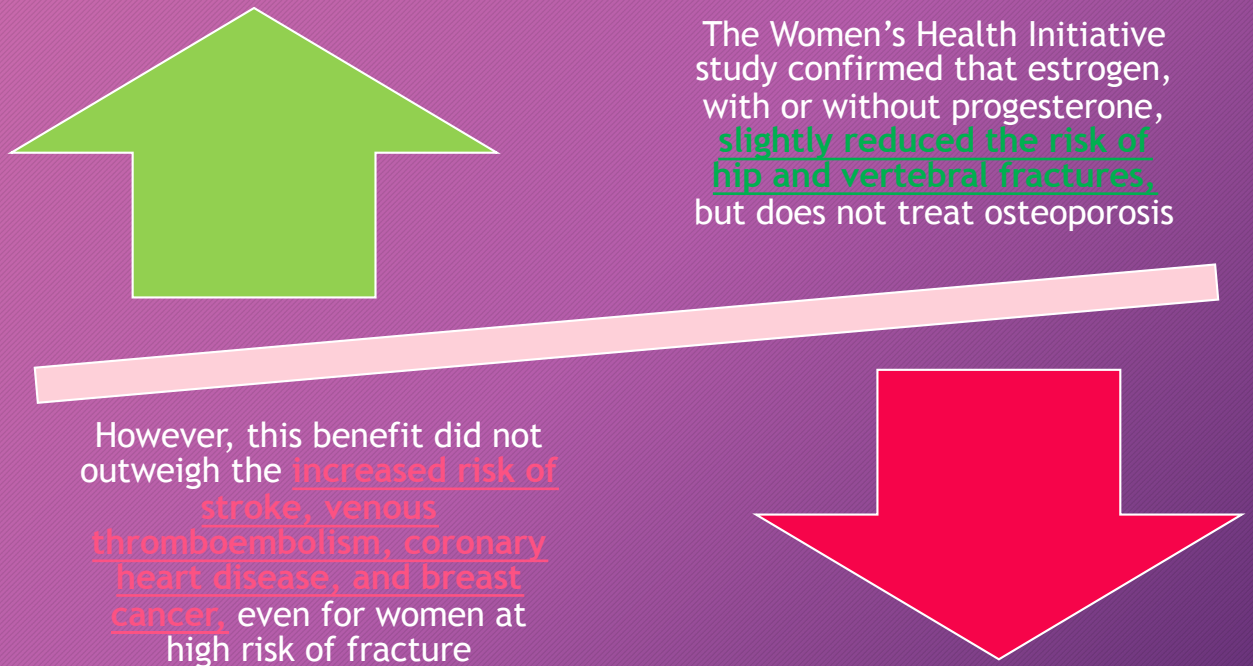
Pharmacologic Treatment – Hormone Therapy



The Women's Health Initiative study confirmed that estrogen, with or without progesterone, slightly reduced the risk of hip and vertebral fractures, but does not treat osteoporosis

However, this benefit did not outweigh the increased risk of stroke, venous thromboembolism, coronary heart disease, and breast cancer, even for women at high risk of fracture

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Summary - Hormone Therapy

- Has been approved for **prevention** of osteoporosis in women
- Is not considered sufficient therapy for women who have experienced an osteoporotic fracture or are at high risk for fractures
- Can be considered for women who choose to take estradiol for other reasons, especially in patients reluctant to use approved osteoporosis medications

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Medication Summary

Table 6. Fracture Risk Reduction by Site[1,2]

Drug	Vertebral Fractures	Nonvertebral Fractures	Hip Fractures
Bisphosphonates			
Alendronate (*Fosamax*, and others)	Yes	Yes	Yes
Ibandronate (*Boniva*, and generics)	Yes	No	No
Risedronate (*Actonel*, and others)	Yes	Yes	Yes
Zoledronic acid (*Reclast*, and generics)	Yes	Yes	Yes
Anti-RANK Ligand Antibody			
Denosumab (*Prolia*, and generics)	Yes	Yes	Yes
Parathyroid Hormone Analogs			
Abaloparatide (*Tymlos*)	Yes	Yes	No
Teriparatide (*Forteo*, and generics)	Yes	Yes	No
Selective Estrogen Receptor Modulator			
Raloxifene (*Evista*, and generics)	Yes	No	No
Conjugated Estrogens/Selective Estrogen Receptor Modulator			
Conjugated estrogens/bazedoxifene (*Duavee*)	Yes	No	No
Sclerostin Inhibitor			
Romosozumab-aqqg (*Evenity*)	Yes	Yes[3]	Yes[3]
Calcitonin			
Calcitonin nasal[4]	Yes	No	No

1. PM Camacho et al. Endocr Pract 2020; 26(Suppl 1):1.
2. Trials may not have been adequately powered to demonstrate fracture risk reduction at these sites.
3. In the ARCH trial, 12 months' treatment with romosozumab followed by alendronate for 12 months reduced nonvertebral and hip fractures compared to 24 months' treatment with alendronate. K Saag et al. N Engl J Med 2017; 277:1417.
4. No published studies are available demonstrating the efficacy of injectable calcitonin for fracture prevention.

Follow Up Testing

- After initiation of treatment, the need for follow-up bone density testing is uncertain, but often is completed **every 2 years after initiation**
- A decrease in BMD could suggest:
  - Treatment nonadherence
  - Inadequate calcium or vitamin D intake
  - Unidentified secondary cause of osteoporosis
  - Treatment failure
- However, a single institution study found that although follow-up DEXA scanning for patients with osteoporosis was performed often, **this rarely led to changes in treatment, even in patients found to have decreased BMD**

Initial DXA BMD	Recheck at
≥-1.5	15 years
-1.6 to -2.0	5 years
-2.1 to -2.4	2 years

Medication Discontinuation/Holiday

- Optimal duration of denosumab treatment is unclear. Current recommendations:
  - Treat for 5 to 10 years
  - Reassess fracture risk at those time points and discontinue if fracture risk is no longer high
  - When discontinuation is indicated or desired, begin oral bisphosphonate 6 months after last denosumab injection and continue for at least one year
  - If the patient stopping denosumab cannot tolerate an oral bisphosphonate, referral to Endocrinology is recommended

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Medication Discontinuation/Holiday

- Abaloparatide and teriparatide are used for 2 years and romosozumab for 1 year
- These agents are immediately followed by either a bisphosphonate or denosumab

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Medication Discontinuation/Holiday

Bisphosphonate holiday

Scenario	Current Action	Subsequent Action
• Alendronate for 5 years or zoledronic acid for 3 years • Primary fracture prevention • No incident fractures on therapy • Low to moderate fracture risk • Younger patient (age <76) • Current femur neck T-score >-2.5	Discontinue therapy	• Follow clinically and reassess fracture risk including bone density in 5 years (back to start of CPM) • Consider alternative pharmacotherapy if incident fragility fracture or new major clinical risk factor for fracture

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Medication Discontinuation/Holiday

Bisphosphonate holiday

Scenario	Current Action	Subsequent Action
• Alendronate for 5 years or zoledronic acid for 3 years • Primary fracture prevention • High fracture risk • Older patient (age ≥76) • Current femur neck T-score ≤-2.5	Option to discontinue therapy for 2 years	• Follow clinically and reassess fracture risk. Large decline in bone density two or more years after discontinuation requires reassessment (back to start of CPM) • Restart prior drug and treat for an additional 5 years (alendronate) or 3 years (zoledronic acid) • Consider alternative pharmacotherapy if incident fragility fracture or new major clinical risk factor for fracture

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Medication Discontinuation/Holiday

Bisphosphonate holiday

Scenario	Current Action	Subsequent Action
• Alendronate for 5 years or zoledronic acid for 3 years • Secondary fracture prevention • Prevalent vertebral fracture at time of treatment initiation or incident fracture on therapy • High fracture risk • Older patient (age ≥76) • Current femur neck T-score ≤-2.0	Continue therapy • Zoledronic acid: up to 6 years • Alendronate: up to 10 years Alternatively, consider change in medication choice especially if incident fragility fracture or new major clinical risk factor for fracture	• Consider alternative pharmacotherapy if incident fragility fracture or new major clinical risk factor for fracture

Treatment Failure

- Recurrent fractures or declining bone mineral density within 1 year of starting therapy requires review of the management plan.
  - Review of adherence to treatment
  - Exclusion of unidentified or inadequately treated secondary causes of osteoporosis
  - Consideration of the contribution of falls to fracture events
- If osteoporosis medication is to be changed, expert opinion suggests
  - A weaker antiresorptive (eg, ibandronate) could be replaced by a more potent drug of the same class (eg, alendronate)
  - An oral drug (eg, alendronate) could be replaced by an injected drug (eg, zoledronic acid or denosumab)
  - Bisphosphonate could be replaced by an anabolic agent (teriparatide, abaloparatide or romosozumab)

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Resources

- AAFP. Diagnosis and Management of Osteoporosis.
- Dynamed. Osteoporosis.
- AAFP. ACOG Releases Practice Bulletin on Osteoporosis.
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