The Bone Zone: Optimizing the Pharmacist's Role in Osteoporosis Patient Care

Megan Hull, PharmD, BCACP
Andrew Faiella, PharmD, BCACP
Primary Care Clinical Pharmacists
OhioHealth Graduate Medical Education Clinics

Pharmacy Forward: Advancing Practice for a Healthier Tomorrow!

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Disclosure Statement

- Name of Speaker(s) has/have no relevant financial relationship(s) with ineligible companies to disclose.

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- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

At the completion of this activity, the participant will be able to:

- identify patient-specific risk factors and non-traditional patient populations that warrant osteoporosis screening or referral for treatment;
- recommend appropriate pharmacologic regimens for patient cases, considering their FRAX score, comorbidity status, and fracture history; and
- describe key adverse effects associated with major osteoporosis drug classes and formulate effective counseling points to improve patient adherence.

Defining Osteoporosis

Learning Objective #1

Prevalence

- Estimated that 10.2 million people in the US who are age 50 years and older have osteoporosis
- Evidence suggests that use of medications to treat osteoporosis are underutilized and declining
- Incidence of fractures is no longer decreasing

Quality Measures

- The percentage of women 65-75 years of age who received osteoporosis screening

- The percentage of women 67-85 years of age who suffered a fracture and who had <u>either</u> a bone mineral density (BMD) test or <u>prescription for a drug to treat osteoporosis in the 180 days (6 months) after the fracture</u>

NQF: 0053 (2021).

The Plethora of Clinical Guidelines

Guideline	Sponsoring Organization
Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline	The Endocrine Society and the European Society of Endocrinology
Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis—2020 Update	American Association of Clinical Endocrinologists/American College of Endocrinology
Management of Postmenopausal Osteoporosis	American College of Obstetricians & Gynecologists
Evidence-Based Guideline for the Management of Osteoporosis in Men	European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases
2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis	American College of Rheumatology
Pharmacological treatment of primary osteoporosis or low bone mass to prevent fractures in adults: a living clinical guideline from the American College of Physicians	American College of Physicians

Clinical Guidelines Summary – Diagnosis

Guideline	High Risk	Very High Risk
Endocrine Society	Prior spine or hip fracture; **or** T-score ≤ -2.5; **or** FRAX score ≥3% for hip fracture or ≥ 20% for major osteoporotic fracture, especially those with a recent fracture	Multiple spine fracture **and** T-score ≤ -2.5
AACE-ACE 2020	T score ≤ –2.5 at spine, femoral neck, total hip or 33% radius; **or** T score –1.0 to –2.5 and ≥3% for hip fracture or ≥ 20% for major osteoporotic fracture as estimated with use of FRAX	Fracture within previous 12 months; fracture occurring during osteoporosis therapy; multiple fractures; fractures while taking medications causing skeletal harm; T-score <-3.0; High risk of falls; FRAX >4.5% for hip fracture or >30% for major osteoporotic fracture
ACP 2023	T score of –2.5 or less at formal neck, lumbar spine, or both; individualize in those >65 yr of age with osteopenia	No explicit definition

Clinical Guidelines Summary – Treatment

Guideline	High Risk Treatment	Very High Risk Treatment
Endocrine Society	Bisphosphonates, alternative therapy is denosumab; can consider SERMS and ET in specific groups	Teriparatide or abaloparatide; romosozumab if not at high CV risk
AACE-ACE 2020	Alendronate, denosumab, risedronate, zoledronate, ibandronate or raloxifene are alternatives for spine specific therapy only	Abaloparatide, denosumab, romosozumab, teriparatide, zoledronate
ACP 2023	Bisphosphonates or denosumab if CI to are AE from bisphosphonates	Teriparatide or romosozumab followed by antiresportive

Patient-Specific Risk Factors

Slim build

Low calcium intake or little exercise

Early menopause

No pregnancies

Drugs and external factors

Ethnic background*

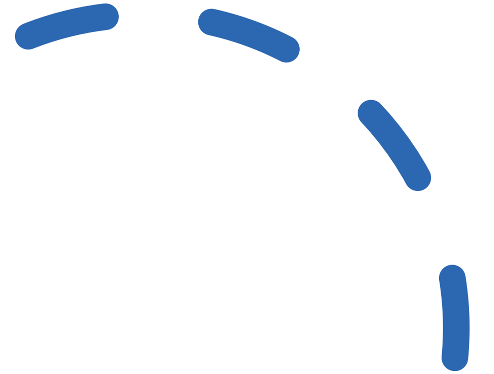
Relatives with osteoporosis

American Association of Clinical Endocrinology (n.d.).

Secondary Osteoporosis Causes: Medications

- Anti-epileptic drugs
- Aromatase inhibitors
- Chemotherapy/ immunosuppressants
- Medroxyprogesterone acetate
- Glucocorticoids
- Gonadotropin-releasing hormone agents
- Heparin
- Lithium
- Proton pump inhibitors
- SSRIs
- SGLT2 inhibitors
- TZDs
- Thyroid hormone (in supraphysiologic doses)

Camacho, et al (2020).



Endocrine Society Guidelines

Measuring Bone Mineral Density: DEXA

Category	T-Score
Normal	-1.0 or above
Low bone mass (osteopenia)	Between -1.0 and -2.5
Osteoporosis	-2.5 or below
Severe or established osteoporosis	-2.5 or below with fragility fracture

Camacho, et al (2020).

Diagnosing Osteoporosis

T-score -2.5 or below in commonly screened areas

Low-trauma spine or hip fracture (regardless of BMD)

T-score between -1.0 and -2.5 **and** fragility fracture of proximal humerus, pelvis, or distal forearm

T-score between -1.0 and -2.5 **and** high FRAX score

Camacho, et al (2020).

Using the FRAX Calculator

Calculates ten-year probability of fracture with or without BMD

Continent/Country	Height	Glucocorticoids
Age	History of previous fracture	Rheumatoid arthritis
Sex	Parent fractured hip	Secondary osteoporosis
Weight	Currently smoking	Alcohol 3 or more units/day
	Femoral neck BMD	

Frax Calculator | FRAXplus® (2026).

Risk is significant if:

major osteoporotic fracture risk is

20%

or greater

or

hip fracture risk is

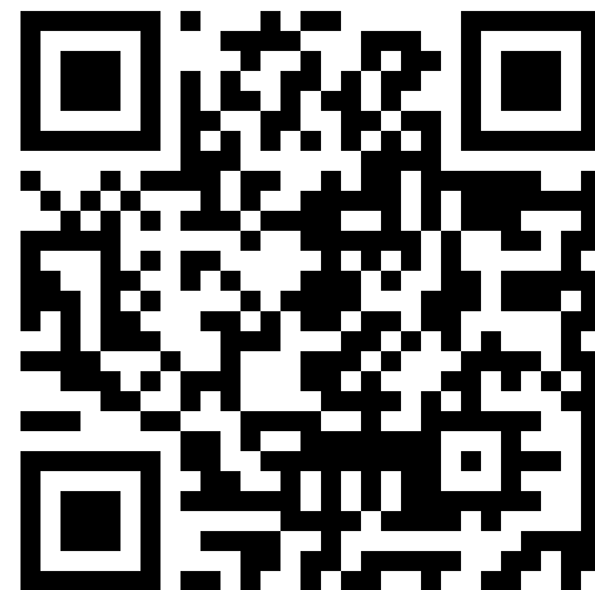
3%

or greater

Frax Calculator | FRAXplus® (2026).

Using the FRAX Calculator

U.S. citizen	Current smoker
68-year-old Asian female	Recently finished 5-day course of prednisone
165 pounds	No history of rheumatoid arthritis
5 feet, 5 inches	Diagnosis of Type 1 diabetes
No history of previous fracture	Drinks 1 beer every weekend
No history of parent fracture	Femoral neck T-score of -2.1



Using the FRAX Calculator

U.S. citizen	Current smoker
68-year-old Asian female	Recently finished 5-day course of prednisone
165 pounds	No history of rheumatoid arthritis
5 feet, 5 inches	Diagnosis of Type 1 diabetes
No history of previous fracture	Drinks 1 beer every weekend
No history of parent fracture	Femoral neck T-score of -2.1

Major osteoporotic fracture risk?

Major hip fracture risk?

Determining Need for Treatment

Low Risk (need to meet all criteria)

- No prior hip or spine fractures
- BMD T-score above -1.0
- Hip fracture risk less than 3%
- Major osteoporotic risk less than 20%

Moderate Risk (need to meet all criteria)

- No prior hip or spine fractures
- BMD T-score above -2.5
- Hip fracture risk less than 3%
- Major osteoporotic risk less than 20%

High Risk (only need to meet one criterion)

- Prior hip or spine fracture
- BMD T-score of 2.5 or below
- Hip fracture risk greater than 3%
- Major osteoporotic risk greater than 20%

Very High Risk (need to meet both criteria)

- Multiple spine fractures
- BMD T-score of -2.5 or below

Eastell, et al (2019).
Fuggle, et al (2024).

Reviewing the Guidelines: Postmenopausal Women

All Postmenopausal Women
1) Lifestyle and nutritional optimization for bone health especially calcium and vitamin D
2) Determine the 10-year fracture risk according to country-specific guidelines

Low-Moderate Risk

Low Risk

Reassess fracture risk in 2–4 yrs

Moderate Risk

OR

High-Very High Risk

(4.2)

(A.2)

(2.1) **Bisphosphonates**
(2.2) Reassess fracture risk in 3–5 yrs
(2.2) (5 yrs for oral, 3 yrs for IV)
(8.1) **Calcium + Vitamin D**
as adjunct therapy

(3.1) **Denosumab**
(3.2) Reassess fracture risk in 5–10 yrs
(8.1) **Calcium + Vitamin D**
as adjunct therapy

(4.1) **Teriparatide or Abaloparatide**
For 2 yrs
(8.1) **Calcium + Vitamin D**
as adjunct therapy

(A.1) **Romosozumab**
For 1 yr
(8.1) **Calcium + Vitamin D**
as adjunct therapy

Low-Moderate Risk
(2.2) Consider a drug holiday
(11.1) Reassess fracture risk every 2–4 yrs
(2.2) If bone loss or patient becomes high risk, consider restarting therapy

High Risk
(2.2) Continue therapy or switch to another therapy

Intolerant to or inappropriate for above therapies

Low-Moderate Risk
Consider giving bisphosphonates and then stopping for a drug holiday
(11.1) Reassess fracture risk every 1–3 yrs
If bone loss, fracture occurs, or patient becomes high risk, consider restarting therapy

High Risk
(3.2) Continue therapy or switch to another therapy

Age <60 or <10 yrs past menopause Low VTE risk

Age >60

No vasomotor symptoms
High breast cancer risk

With vasomotor symptoms

(5.1) **SERM (raloxifene, bazedoxifene)**

(6.1 + 6.2) **HT (no uterus, Estrogen; with uterus, Estrogen + Progestin) or Tibolone**

Consider (in order):
1) SERM (5.1)
2) HT/Tibolone (6.1+6.2)
3) Calcitonin (7.1)
4) Calcium + Vitamin D (8.2)

Eastell, et al (2019).
Fuggle, et al (2024).

Pharmacological treatment is recommended for men:

- aged 50 or older who have had spine or hip fractures
- those with T-scores of less than -2.5 or below
- at high risk of fracture based on low bone mineral density, and/or
- clinical risk factors

FDA-Approved Drugs for Use In Men

Alendronate

Risedronate

Zoledronic acid

Denosumab

Teriparatide

Reviewing the Guidelines: Men

Watts, et al (2012).
Fuggle, et al (2024).

Drug Holidays - Bisphosphonates

- Appropriate duration of bisphosphonate treatment is unclear
- Adverse event of concern is atypical femur fractures
- Most guidelines recommend "drug holidays" in women who are not at high risk for fracture after 5 years of treatment with oral bisphosphonate and 3 years with IV bisphosphonate
- Treatment of up to 10 years (oral) or 6 years (IV) is suggested in women at high risk
- Resuming after holiday is individualized decision

Walker, et al (2023).

Drug Holidays – Denosumab

- Appropriate duration of denosumab is unclear
  - Endocrine Society reassessing fracture risk after 5 to 10 years of therapy or consider switching therapy in patients who remain at high risk

Walker, et al (2023).

Sequential Drug Therapy

- Limited data to guide decision making
- Antiresorptives can blunt or delay gains from anabolic agents

Walker, et al (2023).

Monitoring During Treatment

- Most guidelines recommend repeat DXA 1 to 2 years after starting or switching therapy
  - After this period, recommendations amongst guidelines are inconsistent
- Nonresponse is a decrease in BMD greater than the least amount of change that can be considered clinically significant
- Decreasing BMD or occurrence of multiple fractures should prompt evaluation

Walker, et al (2023).

First-Line Osteoporosis Treatment

Learning Objective #2 and 3

Nonpharmacologic Add-Ons

- Adequate calcium of 1,200mg daily through dietary sources and supplementation
- Adequate vitamin D with serum 25-hydroxyvitamin D level > 30 ng/mL
- Weight-bearing and strength-training exercises

Bisphosphonates

Alendronate (Fosamax®, Binosto®)	**Risedronate (Actonel®, Atelvia™)**	**Ibandronate (Boniva®)**	**Zoledronic Acid (Reclast®)**
70 mg oral tablet/effervescent tablet/solution taken weekly OR 10 mg oral tablet taken daily	**IR**: 5 mg oral tablet taken daily OR 35 mg oral tablet taken weekly OR 150 mg oral tablet taken monthly **ER**: 35 mg oral tablet taken monthly	150 mg oral tablet taken monthly OR 3 mg IV injection given every 3 months	5 mg IV infusion given once yearly

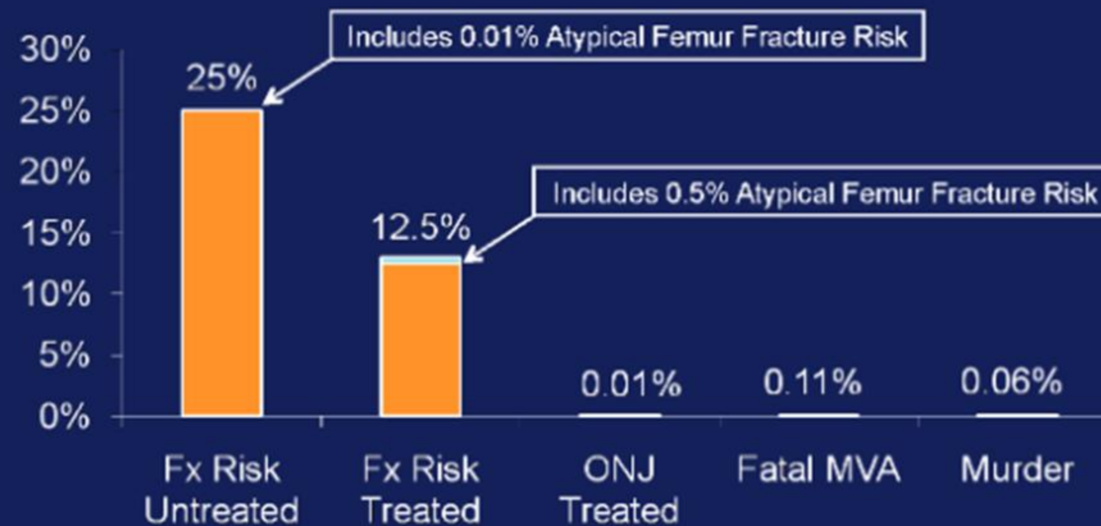
Bisphosphonates

- **Mechanism**: bind to sites of active bone remodeling and reduce activity of bone-resorbing osteoclasts
- **Place in Therapy**:
  - First-line treatment of osteoporosis
  - Non-oral options for those with history of esophageal irritation
  - Consideration of drug holiday after 5-10 years

Bisphosphonates

- **Notable Adverse Effects**:
  - Gastrointestinal mucosal irritation
  - Hypocalcemia
  - Musculoskeletal pain
  - Osteonecrosis of the jaw (ONJ)
  - Atypical femur fractures
- **Counseling Points**:
  - Take oral agents with a full glass of water first thing in the morning, staying upright and waiting 30 minutes before other medications, food, or drinks
  - IV bisphosphonates can cause flu-like illness with first dose

Bisphosphonates



Denosumab

- **Mechanism:** RANKL inhibitor → decreased bone resorption and increased bone mass and strength
- **Place in Therapy:**
  - Those unable to tolerate a bisphosphonate
  - Postmenopausal women at high risk of fracture
  - Men at high risk of fracture receiving androgen deprivation therapy
  - Women at high risk of fracture receiving aromatase inhibitor therapy
  - Duration of therapy: 5 to 10 years, no data on use beyond 10 years

Denosumab (Prolia®)	Denosumab-nxxp (Bildyos®)	Denosumab-bnht (Conexxence®)	Denosumab-bbdz (Jubbonti®)	Denosumab-bmwo (Stoboclo®)
60 mg subcutaneous injection given every six months in a healthcare setting				

Amgen. (2025). Prolia® (denosumab). [package insert].

Denosumab

- **Notable Adverse Effects:**
  - Hypocalcemia
  - Osteonecrosis of the jaw (ONJ)
  - Atypical femur fractures
- **Counseling Points:**
  - Increased risk of new vertebral fractures upon discontinuation
  - Potential for bone, joint, and muscle pain

Denosumab (Prolia®)	Denosumab-nxxp (Bildyos®)	Denosumab-bnht (Conexxence®)	Denosumab-bbdz (Jubbonti®)	Denosumab-bmwo (Stoboclo®)
60 mg subcutaneous injection given every six months in a healthcare setting				

Amgen. (2025). Prolia® (denosumab). [package insert].

Second-Line Osteoporosis Treatment

Learning Objective #2 and 3

Parathyroid Hormone

- **Mechanism:** formulation of PTH, which stimulated osteoblast function and increases calcium absorption
- **Place in Therapy**:
  - Third-line for treatment of osteoporosis
  - Maximum length of therapy: 2 years

Teriparatide (Forteo®)	Abaloparatide (Tymlos®)
20 mcg subcutaneous injection taken daily	80 mcg subcutaneous injection taken daily

Parathyroid Hormone

- **Notable Adverse Effects**: hypercalcemia, nausea, orthostatic hypotension, elevated uric acid levels (urolithiasis)
- **Counseling Points**:
  - Contraindicated in those with primary hyperparathyroidism, Paget's disease, pregnancy and breastfeeding
  - Daily injections
  - Expensive

Teriparatide (Forteo®)	**Abaloparatide (Tymlos®)**
20 mcg subcutaneous injection taken daily	80 mcg subcutaneous injection taken daily

Romosozumab

- **Mechanism**: sclerostin inhibitor
- **Place in Therapy:**
  - Initial osteoporosis treatment in those at very high fracture risk
    - T-score less than -3 in any region
    - T-score less than -2.5 with history of fragility fracture
    - Severe or multiple prior vertebral fractures
  - Alterative treatment in those who have failed other treatments or unable to use first-line therapies

Romosozumab-aqqg (Evenity®)
Two consecutive subcutaneous injections given every month in a healthcare setting

Amgen. (2019). Evenity® (romosozumab). [package insert].

Romosozumab

- **Notable Adverse Effects:**
  - Contraindicated in patients with history of MI or stroke
  - Hypocalcemia
  - ONJ
  - Atypical femur fractures
- **Counseling Points:**
  - Maximum length of therapy = 12 months
  - Potential for headaches and arthralgias

Romosozumab-aqqg (Evenity®)
Two consecutive subcutaneous injections given every month in a healthcare setting

Amgen. (2019). Evenity® (romosozumab). [package insert].

Osteoporosis Treatment

Learning Objective #2 and 3

SERM

- **Mechanism**: estrogen agonist in bone to decrease bone resorption, increasing BMD and decreasing fractures
- **Place in Therapy (must meet all criteria):**
  - Those < 60 years of age OR those < 10 years post-menopause
  - Low VTE risk
  - No vasomotor symptoms
  - High breast cancer risk

Raloxifene (Evista®)	Bazedoxifene with Conjugated Estrogens (Duavee®)
60 mg oral tablet taken daily	20 mg bazedoxifene + 0.45 mg conjugated estrogens oral tablet taken daily

SERM

- **Notable Adverse Effects:**
  - VTE
  - Hot flashes
  - Peripheral edema
  - Arthralgias and leg cramps

Raloxifene (Evista®)	Bazedoxifene with Conjugated Estrogens (Duavee®)
60 mg oral tablet taken daily	20 mg bazedoxifene + 0.45 mg conjugated estrogens oral tablet taken daily

Hormone Therapy

- **Place in Therapy:**
  - Those < 60 years of age OR those < 10 years post-menopause
  - Low VTE risk
  - With vasomotor symptoms
- **Notable Adverse Effects:**
  - VTE

Estrogen (no uterus)	Estrogen + Progesterone (has uterus)	Tibolone (Tibella®) *Not available in US*
		2.5 mg oral tablet taken daily

Applying the Information:

Patient Cases

Learning Objective #2 and 3

Case #1

A 78-year-old black woman just completed her DEXA scan and is following up with her PCP to determine if she needs to start a medication. Patient has no personal or familial history of fractures. She does not smoke, drink alcohol, or use illicit drugs. Past medical history includes osteoarthritis, hypertension, diabetes, hypothyroidism and went through menopause at 52.

Pertinent Labs	Vitals	Medications
eGFR: 69 mL/min/1.73 m^2 SCr: 0.92 mg/dL HgA1c: 7.2% 25(OH) D: 19 mg/mL	Ht: 61 in (155 cm) Wt: 141 lbs (64 kg) BP: 134/82 mmHg P: 86 bpm RR: 18 bpm	metformin 1000 mg twice daily levothyroxine 50 mcg daily lisinopril 10 mg daily rosuvastatin 5 mg daily

Case #1

DEXA Results:

Lumbar spine: The bone mineral density in the lumbar spine including the L1-L4 levels is measured at 0.984 g/cm^2, which corresponds to a **T-score of -1.6 and a Z-score of -0.5.**

Hip: The bone mineral density in the total hip is measured at 0.872 g/cm^2 corresponding to a **T-score of -1.1 and a Z-score of -0.2.**

Femoral neck: The bone mineral density of the femoral neck is measured at 0.734 g/cm^2 corresponding to a **T-score of -2.2 and a Z-score of -1.1.**

Case #1

What is the patient's FRAX score?

	US (Black)	US (Caucasian)
Major osteoporotic	7.4%	16%
Hip Fracture	2.2%	5.0%

Does the patient qualify for treatment?

Case #1

Race in FRAX

- US FRAX calculator is unique in how it handles race
- Concerns that calculator contributes to health disparities
- No consensus amongst professional bodies
  - American Society for Bone and Mineral Research (ASBMR) - recommends creation of new model that does not use race/ethnicity
  - International Osteoporosis Foundation (IOF)- single race FRAX model would decrease accuracy of tool and lead to overtreatment of non-white individuals

Case #1

What is the patient's FRAX score?

	US (Black)	US (Caucasian)
Major osteoporotic	7.4%	16%
Hip Fracture	2.2%	5.0%

Does the patient qualify for treatment?

Shared decision making

What are non-pharm recommendations for preventing falls?

Case #2

Patient is a 65-year-old postmenopausal (menopause at 44 years old) caucasian female who presents to PCP office for her MWV. Patient has personal history of a fragility fracture prior to starting treatment. She has been on her current treatment for 18 months. Her height is stable. Patient is a former smoker (quit 2 years ago, pack history 30 years). She does not consume alcohol or use illicit drugs. Past medical history includes, Osteoporosis, Asthma-COPD Overlap and depression.

Pertinent Labs	Vitals	Medications
eGFR: 75 mL/min/1.73 m^2 SCr: 0.90 mg/dL 25(OH) D: 20 mg/mL	Ht: 58 in (147 cm) Wt: 120 lbs (54.5 kg) BP: 114/79 mmHg P: 78 bpm RR: 19 bpm	Teriparatide 20 mcg once daily Budesonide-Formoterol 160/4.5 mcg 1 puff twice daily Tiotropium Handihaler 18 mcg daily Albuterol HFA 1-2 puffs every 4-6 hours as needed Desvenlafaxine 100 mg daily Rosuvastatin 5 mg daily

Case #2

Initial DEXA Results

HISTORY: 65-year-old postmenopausal white female for osteoporosis with prior fragility fracture

Lumbar spine: The bone mineral density in the lumbar spine including the L1-L4 levels is measured at 0.675 g/cm^2, which corresponds to a **T-score of -3.4 and a Z-score of -1.4.**

Hip: The bone mineral density in the total hip is measured at 0.575 g/cm^2 corresponding to a **T-score of -3.4 and a Z-score of -1.4.**

Femoral neck: The bone mineral density of the femoral neck is measured at 0.520 g/cm^2 corresponding to a **T-score of -3.6 and a Z-score of -1.8.**

Case #2

Follow-Up DEXA Results after 18 months of teriparatide

HISTORY: 65-year-old postmenopausal female; osteoporosis with prior fragility fracture

Lumbar spine: The bone mineral density in the lumbar spine including the L1-L4 levels is measured at 0.645 g/cm^2, which corresponds to a **T-score of -2.7 and a Z-score of -1.0.**

Hip: The bone mineral density in the total hip is measured at 0.645 g/cm^2 corresponding to a **T-score of -2.7 and a Z-score of -1.0.**

Femoral neck: The bone mineral density of the femoral neck is measured at 0.590 g/cm^2 corresponding to a **T-score of -2.4 and a Z-score of -0.8.**

Case #2

What is a suitable treatment plan for this patient?

What is a suitable monitoring program for this patient?

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Megan Hull, PharmD, BCACP
Megan.Hull@ohiohealth.com

Andrew Faiella, PharmD, BCACP
Andrew.Faiella@ohiohealth.com

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