

OSTEOPOROSIS:

Healthcare Provider (HCP) Diagnosis & Treatment Factsheet

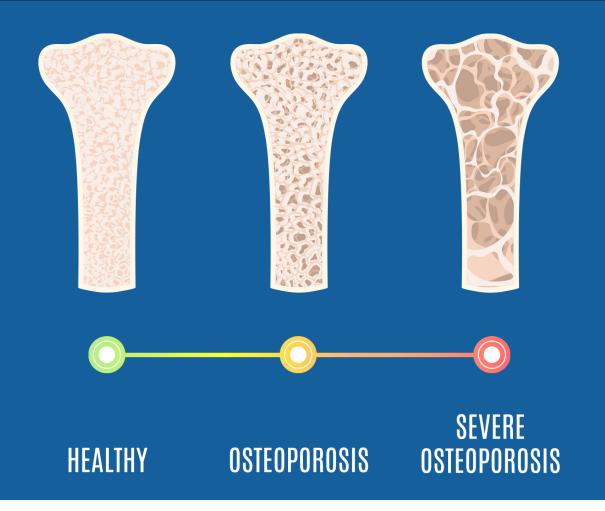
WHAT IS OSTEOPOROSIS?

Osteoporosis is a disease characterized by low bone density, deterioration of bone tissue, disrupted bone microarchitecture, compromised bone strength, and risk of fracture.

Osteoporosis is the most common metabolic bone disease. It is a subclinical condition until complicated by fracture(s). These fractures place an enormous medical and personal burden on individuals who suffer from them and take a significant economic toll. Any new fracture in an adult aged 50 years or older signifies an elevated risk for subsequent fractures, particularly in the year following the initial fracture. Osteoporosis is a risk factor for fracture, just as hypertension is for stroke and hypercholesterolemia is for heart disease.

Approximately 1 in 2 women and up to 1 in 4 men aged 50 and older will break a bone due to osteoporosis or low bone mass.

OSTEOPOROSIS STAGES



EVALUATION/DIAGNOSIS OF OSTEOPOROSIS

THERE ARE 3 WAYS THAT OSTEOPOROSIS CAN BE DIAGNOSED.

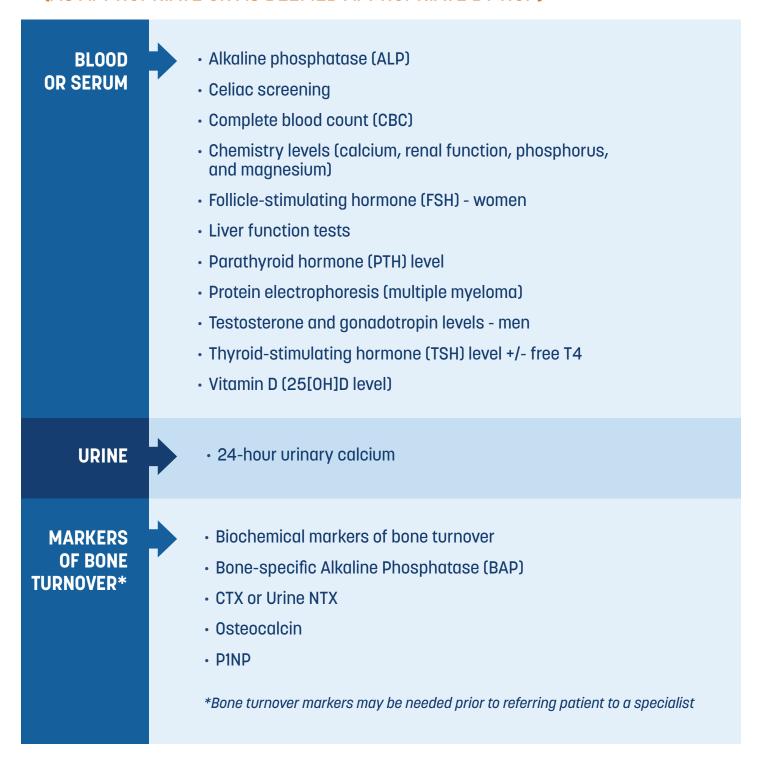
T-score, a number output of DXA scan, indicates fragility of bone. Normal is zero (0). The more negative the number, the weaker the bones and the more likely they are to break. If the T-score is -2.5 BONE MINERAL or below (such as -3.0), then the patient has osteoporosis. DENSITY (BMD) If a patient over the age of 50 years has had a fracture of the spine, hip, wrist, humerus (shoulder), rib, and/or pelvis, then FRACTURE they probably have osteoporosis (fractures of toes, fingers, nose and skull not included). A fracture of the spine or hip means osteoporosis regardless of the T-score. The occurrence of a fracture suggests that bones are weaker than they should be and that further evaluation may be needed. In older adults, even fractures with major trauma, such as an auto accident, may be a sign of osteoporosis. FRAX[®] is a country and ethnicity specific fracture risk calculator that is included in the software of most DXA systems and is accessible online for anyone at *https://frax.shef.ac.uk/FRAX/index.aspx* With input of bone density, age, sex, height, weight, and answers to 7 questions, FRAX[®] calculates the chances of having different types of fractures in the next 10 years. If the 10-year probability of major osteoporotic fracture (spine, hip, shoulder, or forearm) is 20% or more, or the 10-year probability of hip fracture is 3% or more, then a diagnosis of osteoporosis can be made. FRAX[®] can be used before age 65 if patient is at risk, to help you evaluate their fracture risk. The FRAX[®] model accepts ages between 40 and 90 years.

SECONDARY CAUSES OF OSTEOPOROSIS

PRIOR TO INITIATING PHARMACOLOGIC ANTIFRACTURE TREATMENT, PATIENTS SHOULD BE EVALUATED FOR SECONDARY CAUSES OF OSTEOPOROSIS.

ENDOCRINE OR METABOLIC CAUSES	NUTRITIONAL/ GI CONDITIONS	DRUGS	DISORDERS OF COLLAGEN METABOLISM	OTHER
 Acromegaly Diabetes mellitus Type 1 Type 2 Growth hormone deficiency Hypercortisolism Hyperparathyroidism Hypogonadism Hypophosphatasia Porphyria Pregnancy 	 Alcoholism Anorexia nervosa Calcium deficiency Chronic liver disease Malabsorption syndromes/ malnutrition (including celiac disease, cystic fibrosis, Crohn's disease, and gastric resection or bypass) Total parenteral nutrition Vitamin D deficiency 	 Anti-epileptic drugs Aromatase inhibitors Chemotherapy/ immunosuppressants Medroxyprogesterone acetate Glucocorticoids Gonadotropin- releasing hormone agents Luteinizing hormone (LH) Follicle-stimulating hormone (FSH) Heparin Lithium Proton pump inhibitors Selective serotonin- reuptake inhibitors SGLT2-inhibitors Thiazolidinediones Thyroid hormone (in supraphysiologic doses) 	 Ehlers-Danlos syndrome Homocystinuria due to cystathionine deficiency Marfan syndrome Osteogenesis imperfecta 	 AIDS/HIV Ankylosing spondylitis Chronic obstructive pulmonary disease Gaucher disease Gaucher disease Hemophilia Hypercalciuria Immobilization Major depression Major depression Myeloma and some cancers Organ transplantation Organ transplantation Renal insufficiency/ failure Renal tubular acidosis Rheumatoid arthritis Systemic mastocytosis Thalassemia

PRETREATMENT LABORATORY TESTS (AS APPROPRIATE OR AS DEEMED APPROPRIATE BY HCP)



Given that falls are the leading cause of fracture in older adults, it is critical that all patients being considered for treatment receive comprehensive fall risk evaluation and referral for athome safety assessment and adaptive modifications.

WHO TO TREAT? WHEN TO TREAT?

POSTMENOPAUSAL WOMEN AND MEN AGED 50 AND OLDER PRESENTING WITH THE FOLLOWING SHOULD BE CONSIDERED FOR TREATMENT.

HIP OR VERTEBRAL FRACTURE	 Risk triples after the first vertebral fracture and increases up to 23 times after the third. Fracture incidence declines in patients with spine or hip fractures who are treated with approved pharmacologic agents. This is true for patients with previous fractures, whether their T-score classification is osteopenia (low bone mass) or osteoporosis.
WRIST OR FOREARM FRACTURE PLUS LOW T-SCORE ≤ -2.5 AND LOWER BMD	 Treatment should be considered for any postmenopausal woman or a man aged ≥50 years with low BMD who fractures a wrist or forearm. T-score is less predictive of future fracture risk than the fracture itself. Pharmacotherapy prevents fracture in patients with osteoporosis by BMD-DXA at any clinically relevant site (femoral neck, total hip, or lumbar spine).
LOW BONE MASS AND FRAX® SCORE ABOVE TREATMENT THRESHOLD	 A BMD T-score between -1.0 and -2.5 at the femoral neck or lumbar spine AND A 10-year probability of a hip fracture ≥3% or a 10-year probability of a major osteoporosis related fracture ≥20% based on the US-adapted FRAX®* algorithm are indicative of high fracture risk and need for pharmacologic intervention. *FRAX® score should be calculated by provider to ensure accuracy

All patients being considered for treatment of osteoporosis should also be counseled on risk reduction including adequate intake of calcium, vitamin D sufficiency, smoking cessation, avoidance of excessive alcohol intake, and optimization of physical activities that include weight-bearing, muscle-strengthening, and balance exercises.

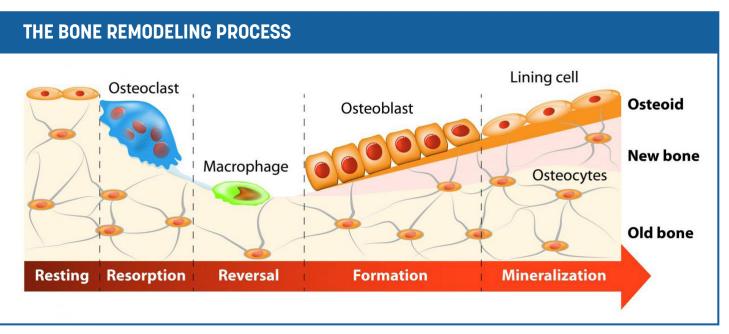
OSTEOPOROSIS MEDICATION AND TREATMENT THERE ARE MANY SAFE AND EFFECTIVE MEDICATIONS AVAILABLE TO SLOW DOWN THE LOSS OF BONE AND REDUCE THE RISK OF BREAKING A BONE.

CLASS AND DRUG	BRAND NAME	FORM	FREQUENCY	GENDER		
ANTIRESORPTIVE AGENTS						
BISPHOSPHONATES						
ALENDRONATE	Fosamax®, Fosamax Plus D™	Oral (tablet, solution)	Daily/Weekly	Women & Men		
ALENDRONATE	Binosto®	Oral (effervescent tablet)	Weekly	Women & Men		
IBANDRONATE	Boniva®	Oral (tablet)	Monthly	Women		
IBANDRONATE	Boniva®	Intravenous (IV) injection	Every 3 months	Women		
RISEDRONATE	Actonel®	Oral (tablet)	Daily/Weekly/Twice Monthly/Monthly	Women & Men		
RISEDRONATE	Atelvia®	Oral (tablet)	Weekly	Women		
ZOLEDRONIC ACID	Reclast®	Intravenous (IV) infusion	One time per year/ Once every two years	Women & Men		
RANK LIGAND (RANKL) INI	HIBITOR					
DENOSUMAB	Prolia®	Injection	Every 6 Months	Women & Men		
ANABOLIC AGENTS						
SCLEROSTIN INHIBITOR						
ROMOSOZUMAB-AQQG	Evenity®	Injection	2 injections once monthly for 12 months	Women		
PARATHYROID HORMONE	(PTH) ANALOG					
TERIPARATIDE	Forteo®	Injection	Daily	Women & Men		
TERIPARATIDE	Bonsity®	Injection	Daily	Women & Men		
PARATHYROID HORMONE-RELATED PROTEIN (PTHRP) ANALOG						
ABALOPARATIDE	Tymlos®	Injection	Daily	Women & Men		
ESTROGEN						
ESTROGEN* (HORMONE TH	IERAPY)					
ESTROGEN	Multiple Brands	Oral (tablet)	Daily	Women		
ESTROGEN	Multiple Brands	Transdermal (skin patch)	Twice Weekly/Weekly	Women		
ESTROGEN AGONISTS/ANTAGONISTS - also called Selective Estrogen Receptor Modulators (SERMs)						
RALOXIFENE	Evista®	Oral (tablet)	Daily	Women		
TISSUE SPECIFIC ESTROGI	EN COMPLEX (TSEC)					
ESTROGEN/BAZODOXIFENE	Duavee®	Transdermal (skin patch)	Twice Weekly/Weekly	Women		

*Estrogen is also available in other preparations including a vaginal ring, cream, by injection and as an oral tablet taken sublingually (under the tongue). The vaginal preparations do not provide significant bone protection.

BONE REMODELING

BONE REMODELING IS A PROCESS IN WHICH NEW BONE TISSUE GRADUALLY REPLACES OLD BONE TISSUE. THIS RELATIONSHIP IS VITAL TO MAINTAIN NORMAL CALCIUM LEVELS IN OUR BLOOD.



IN PATIENTS RECEIVING OSTEOPOROSIS PHARMACOLOGIC TREATMENT:

- Routinely reassess risk for fracture, patient satisfaction and adherence with therapy, and need for continued or modified treatment.
- Reassess patient and BMD status for consideration of a drug holiday after 5 years of oral and 3 years of intravenous bisphosphonate in patients who are no longer at high risk of fracture (T-score ≥ - 2.5, no new fractures).
- At each healthcare encounter, ask open-ended questions about treatment to elicit patient feedback on possible side effects and concerns.
- For geriatric patients, provider should ask about falls and fall risks.

ADDITIONAL RESOURCES

- <u>BHOF's Clinician's Guide to Prevention and Treatment of Osteoporosis</u>
- <u>American Association of Clinical Endocrinologists/American College of Endocrinology</u> <u>Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal</u> <u>Osteoporosis–2020 Update</u>
- <u>BHOF Dental Risk Response Letter</u>
- Osteoporosis management: Use a goal-oriented, individualized approach



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