Initial Evaluation for Osteoporosis

All postmenopausal women age ≥50 years of age should undergo clinical assessment for osteoporosis and a detailed history, physical exam, and clinical fracture risk assessment with Fracture Risk Assessment tool (FRAX®)

Note: FRAX age 40-90, Saudi FRAX in process of endorsement. Use USA white as per Saudi Osteoporosis Society SOS1). Or the Kuwaiti FRAX (similar hip fracture incidence to Saudi Arabia ) until the Saudi FRAX is available

<table>
<thead>
<tr>
<th>History</th>
<th>Exam</th>
<th>FRAX Clinical risk factors in FRAX®</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prior osteoporosis-related fractures</td>
<td>• Height loss (&gt;2cm prospectively)</td>
<td>• age</td>
</tr>
<tr>
<td>• Prolonged steroid use</td>
<td>• Weight (BMI)</td>
<td>• Sex</td>
</tr>
<tr>
<td>• Height loss &gt; 6 cm historically</td>
<td>• Low &lt;60 Kg</td>
<td>• body mass index (BMI)</td>
</tr>
<tr>
<td>• Current smoking</td>
<td>• Major loss (≥10% of weight since age 25)</td>
<td>• smoking, alcohol use</td>
</tr>
<tr>
<td>• Excess alcohol ≥ 3 units per day</td>
<td>• Kyphosis</td>
<td>• prior fracture</td>
</tr>
<tr>
<td>• Parental hip fracture</td>
<td>• Rib to pelvis distance &gt;2 FBs</td>
<td>• parental history of hip fracture</td>
</tr>
<tr>
<td>• Falls in past 12 months</td>
<td>• Balance and gait, “Get up and Go” Test</td>
<td>• use of glucocorticoids</td>
</tr>
<tr>
<td>• Other high-risk conditions or medications</td>
<td></td>
<td>• rheumatoid arthritis</td>
</tr>
</tbody>
</table>

Indications for BMD Testing (1)

Menopausal women, and men aged 50-64 years

Menopausal women, and men aged 50-64 years with clinical risk factors for fracture:

• All women ≥40 years who have sustained low-trauma fragility fracture
• Previous fragility fracture or maternal history of hip fracture.
• Hypogonadism or premature menopause (< 45 years), Prolonged secondary amenorrhea (>1 year)
• Prolonged glucocorticoid use ≥ 3 months cumulative use in the past year of prednisone-equivalent dose ≥ 7.5mg daily
• Other high-risk medication use (tamoxifen, thiazolidinedione, Empagliflozin, PPI and anticonvulsant)
• X-ray findings suggestive of osteoporosis such as vertebral fracture, osteopenia identified on X-ray, fragility fracture, loss of height, or thoracic kyphosis (clinical or radiological finding)
• Current smoking
• High alcohol intake
• Low body weight (< 60 kg) or major weight loss (>10% of weight at age 25 years)
• Rheumatoid arthritis
• Other disorders strongly associated with osteoporosis such as primary hyperparathyroidism, type 1 diabetes, osteogenesis imperfecta, uncontrolled hyperthyroidism, Cushing’s disease, chronic malnutrition or malabsorption, chronic inflammatory conditions (e.g., inflammatory bowel disease)

Routine Screening indicated by age

All women age ≥ 60 years in Saudi Arabia (expert opinion screen)
All men age ≥ 65 years
2020 AACE American Association of Clinical Endocrinologists Diagnosis of Osteoporosis in Postmenopausal Women (2)

1. T-score −2.5 or below in the lumbar spine, femoral neck, total proximal femur, or 1/3 radius
2. Low-trauma spine or hip fracture (regardless of bone mineral density)
3. T-score between −1.0 and −2.5 and a fragility fracture of proximal humerus, pelvis, or distal forearm
4. T-score between −1.0 and −2.5 and high FRAX® (or if available, TBS-adjusted FRAX®) 10-year probability for major osteoporotic fracture is ≥20% or the 10-year probability of hip fracture is ≥3% FRAX® = fracture risk assessment tool; TBS = trabecular bone score

For All Osteoporotic Patient Evaluate for Causes of Secondary Osteoporosis Before Start Treatment

- Serum chemistry: TSH, calcium, phosphate, total protein, albumin, liver enzymes, alkaline phosphatases, creatinine, and electrolytes.
- Serum 25-hydroxyvitamin D
- Complete blood cell count
- SPE serum protein electrophoresis if vertebral fracture or suspect multiple myeloma
- X-ray lateral thoracolumbar screen for vertebral fracture if not available from DXA

Recommend pharmacologic therapy Education on lifestyle measures, fall prevention, benefits, & risks of medications

Treatment for Osteoporosis According to Fracture Risk

**LOW RISK** all of the following (4,5):
- No previous fracture,
- Osteopenia (T-score between −1.0 and −2.5) and low FRAX = 10 year major osteoporotic fracture risk < 20% or hip fracture risk < 3%

- Exercise, fall prevention
- Calcium and vitamin D

Reevaluate in 3-5 years

**HIGH RISK** any of:
- Previous osteoporotic fracture >12 months ago (3,6)
- Osteoporosis T score < −2.5 (3,5)
- FRAX 10 year major osteoporotic fracture risk ≥ 20% or hip fracture risk ≥ 3%

First line Alendronate If can’t tolerate oral bisphosphonate option of injectable bisphosphonate Zoledronate or Denosumab

Alternative is raloxifene

Reassess yearly for response to therapy and fracture risk DEXA after 1.5-2 years

**VERY HIGH RISK** any of:
- Fracture within the past 12 months (3,6)
- Recurrent or multiple fractures (3,5)
- Fracture while on treatment for osteoporosis (3)
- Fracture while on glucocorticoids or other bone harmful medication (3)
- Very low T scores < -3 (5)
- FRAX 10 year major osteoporotic fracture risk ≥ 30% or hip fracture risk ≥ 4.5%
- Advanced age, frailty, increased fall risk (2)
- Secondary osteoporosis or decreased kidney function

Referral to osteoporosis specialist

First line anabolic treatment (2):
- Abaloparatide or Teriparatide for up to 2 years or Romosozumab for 1 year followed by Sequential therapy with oral or injectable antiresorptive agent

Alternative treatment: Denosumab

Continue therapy until the patient is no longer high risk and ensure transition with another antiresorptive agent. or zoledronate

If stable, continue therapy for 6 years, Consider a drug holiday after 6 years of IV zoledronate. During the holiday, an anabolic agent or a weaker antiresorptive such as raloxifene could be used. If progression of bone loss or recurrent fractures, consider switching to abaloparatide, teriparatide or romosozumab

Reassess yearly for response to therapy and fracture risk DEXA after 1.5-2 years

Increasing or stable BMD and no fracture

Progression of bone loss or recurrent fractures

1. Assess compliance. Switch to injectable antiresorptive if noncompliant with oral agent
2. Re-evaluate for causes of secondary osteoporosis and factors leading to suboptimal response to therapy
3. Referral to osteoporosis specialist.

Consider a drug holiday after 5 years of oral and 3 years of IV bisphosphonate therapy. Resume therapy when a fracture occurs, BMD declines beyond least significant change

Exercise, fall prevention
Calcium and vitamin D
Reevaluate in 3-5 years
**SERIALS (FDA)**

60 mg/t.i.d.

**RATIONAL**

 sitcom medication

| In Pregnancy: Women who plan to breastfeed
| Risk of postpartumوف risk of Thyrotoxicosis: ON, discontinuation of postpartum
| Government: Treatment for Thyrotoxicosis
| SE: Hypersensitivity: Have a moderate risk of postpartum

- Consider during the 3rd trimester
- Read the instructions before starting treatment

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**CONTRAINdications**

| 1) Hypersensitivity
| 2) Hyperthyroidism

**SPECIAL INSTRUCTIONS**

- Patient should not be down on their back, eat, or drink for at least 30 minutes after taking medication.
- Tablets should be swallowed as whole with at least 8 ounces (240 ml) of plain water (not milk, water, coffee, juice, or any other liquid).
- Medications should be taken an hour before or an hour after food, milk, or any other nourishment.

**PRECAUTIONS**

- In pregnant women, thyroid patients with a history of renal stones
- In patients with hypocalcemia and patients with a history of renal stones
- Instruction: Calcium should be taken with meals. For better absorption, calcium should not be taken with iron (absorption may be decreased)

**AVOIDANCE**

- Pregnant women (600 mg/d)
- Postpartum women (1000 mg/d)

**VITAMIN D:**

- Calcitonin
- Calcium

### Instructions for Use

- Exposure to sun for 10-15 min 2-3 times/week
- In patients with hypocalcemia and patients with a history of renal stones
- In patients with hypocalcemia and patients with a history of renal stones
**Recommend:** Education on lifestyle measures, fall prevention, benefits and risks of medications

<table>
<thead>
<tr>
<th>Exercise type /benefits</th>
<th>Frequency</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Posture exercises</strong> keep you standing tall, not stooped.</td>
<td>Daily 10 min</td>
<td>Pay attention to your posture posture when you stand and sit, do back exercises that extend your spine.</td>
</tr>
<tr>
<td><strong>Balance exercises</strong> help you be more stable on your feet. You can walk more easily. Good balance helps prevent falls.</td>
<td>Daily 20 min</td>
<td>walk heel to toe, reduce base of support, shift your weight, respond to things that upset your balance.</td>
</tr>
<tr>
<td><strong>Strength exercises</strong> keep you strong and fit.</td>
<td>2 times per week</td>
<td>Exercise for leg, arm, chest, shoulder and back. Use body weight against gravity, band and weights *</td>
</tr>
<tr>
<td><strong>Aerobic physical activity</strong> (moderate to vigorous intensity) improves your overall health. It can reduce your risk of disease. It may improve your bone strength.</td>
<td>150 minutes per week</td>
<td>Do aerobic physical activity for about 20 to 30 minutes per day. Exercise for at least 10 minutes at a time. In total, do 150 minutes or more per week.* If you are new to exercise or if you have had a spine fracture, start at low to moderate intensity — 3 to 6 on the scale*</td>
</tr>
</tbody>
</table>

*Refer to physical therapy for advice for proper exercise for each patient

**Give patient medication card** when starting the treatment this is essential for collaborative medical care between specialist and primary care example: Abaloparatide or Teriparatide taken once in life time for up to 2 years and need to be followed by antiresorptive treatment. Moreover, it is essential to know when the patient can go for drug holiday.

Medication: _________________________________________________________________
Calcium: Dietary sources: ______________ mg Supplements: ______________ mg
Vitamin D: __________________________________________________________________

Exercise: ___________________ minutes daily / weekly

Fall Prevention advice ______

Follow up DXA / labs in ___________ months. Return visit in _________ months

References:
2. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS/ AMERICAN COLLEGE OF ENDOCRINOLOGY CLINICAL PRACTICE GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS— 2020 UPDATE Endocr Pract. 2020;26(Suppl 1)