Adult Osteoporosis Screening and Treatment Guidelines

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ICSI 2017 Algorithm for the Diagnosis and Treatment of Osteoporosis

***For Screening and Treatment Guideline Algorithm for Postmenopausal Women, see **Appendix Figure 1**

ICSI
Institute for Clinical Systems Improvement

Health Care Guideline:

Diagnosis and Treatment of Osteoporosis

Ninth Edition
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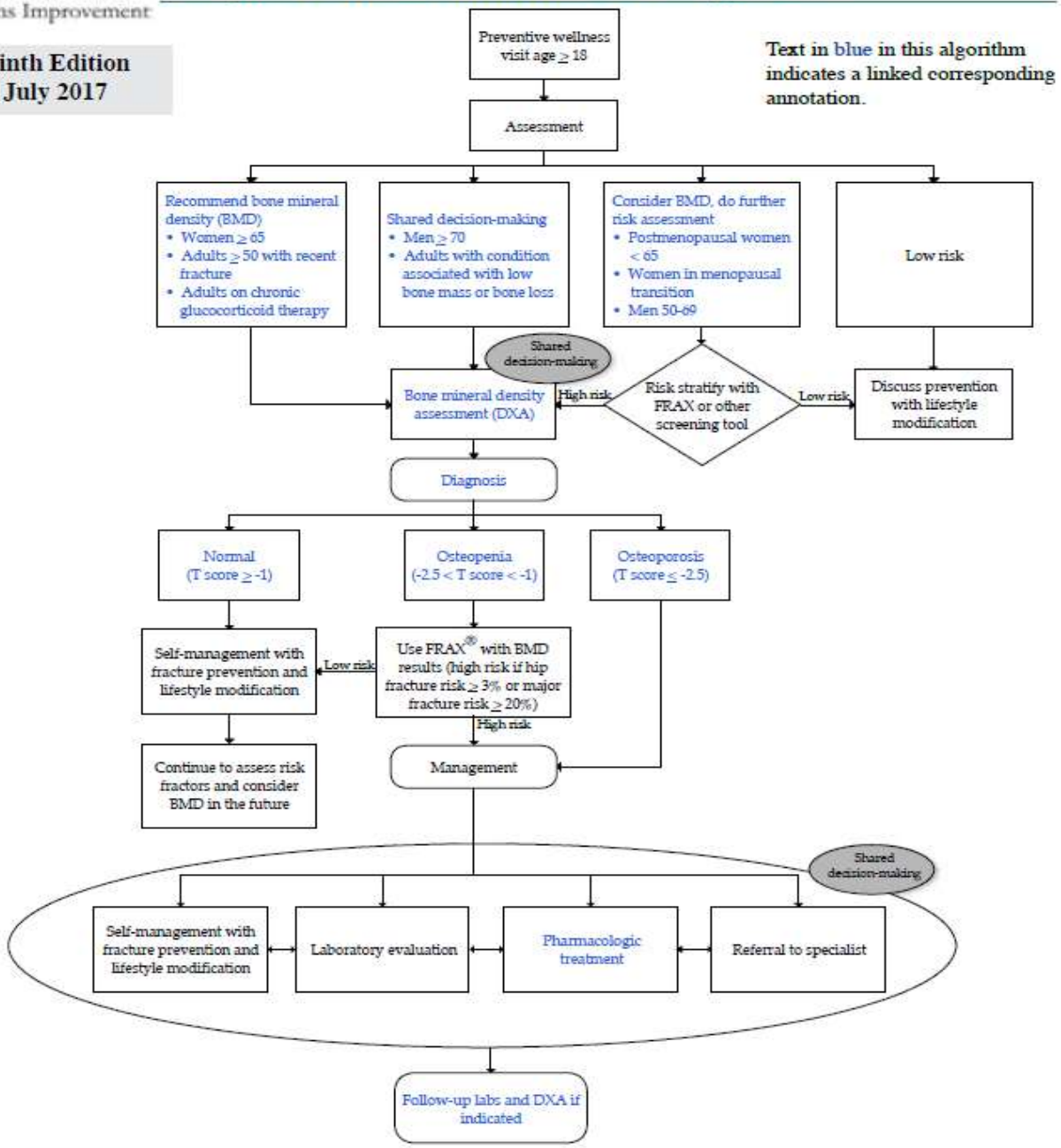

Return to Table of Contents

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Osteoporosis Screening and Treatment Guideline

A summary of clinical recommendations for screening, repeat scanning and treatment options is provided in this guideline.

Lifestyle Modification Recommendations for Bone Health Maintenance

1. **Adequate Calcium Intake** recommended in all patients of both genders (Appendix Table 2)
    a. Dietary intake preferable but supplementation often needed to accomplish goals
    b. Daily recommendations of calcium: (NIH)
        i. Women 19-50 years, Men 19-70 years: 1000 mg/day
        ii. Women ≥51 and Men >70: 1200 mg/day
2. **Adequate Vitamin D intake** and treatment of vitamin D deficiency (Appendix Table 2)
    a. Daily recommendations for vitamin D
        i. Adults <50: 400-800 IU daily
        ii. Adults ≥50: 800-1000 IU daily (NOF)
    b. Maintain serum 25-hydroxyvitamin D (25[OH]D) level to ≥30 ng/ml
        i. Treat with 50,000 IU once weekly for 8-12 weeks, follow with maintenance dose of 1500-2000 IU daily
        ii. Many will need more than general recommendations of vitamin D
        iii. High prevalence of deficiency in limited sun exposure, dark skin, and obese individuals
3. **Physical Activity** recommended lifelong for all ages (ICSI)
    a. Regular weight-based and muscle-strengthening exercise reduces risk of falls and fractures by improving agility, strength, posture, and balance
    b. May modestly increase bone density
4. Achieve and maintain **normal BMI** of 20-25 kg/m^2 (ICSI)
    a. Low body mass is strong risk factor for osteoporosis and fracture (ICSI)
5. **Fall Prevention**
    a. Home safety assessment and modification
    b. Gradual withdrawal of psychotropic medication, if possible
    c. Correction of visual impairments
    d. Consider hip protectors in those with high risk of falling
6. **Cessation of tobacco** use and **avoidance of excessive alcohol** intake
    a. Tobacco use detrimental to skeleton and overall health; address cessation at every visit (ICSI)
    b. Excess alcohol may be detrimental to bone health and increases fall risk (NOF): limit alcohol use to no more than 1 drink/day for women, no more than 2 drinks/day for men (ICSI)
7. Treat/Modify **secondary causes** (other disease processes or medications) of osteoporosis whenever possible (see Table 3 and 4)

Recommendations for Baseline Bone Mineral Density Screening (Central DEXA) - See Appendix Table 5

Assess fracture risk with the Fracture Risk Assessment Tool (**FRAX**) **during initial evaluation** for osteoporosis. Bone mineral density testing (BMD) by central dual-energy X-ray absorptiometry (DEXA) is recommended for:

1. All postmenopausal women aged ≥65 years
2. Men aged ≥70 years, shared decision making (ICSI, NOF)
3. Women <65 years whose fracture risk is ≥9.3% from FRAX analysis or are considered to be at fracture risk (NOF, USPSTF) (also list by ICSI of risk factors)
4. Post-menopausal women of any age with additional risk factors for osteoporosis or fracture
    a. Family history of osteoporosis with fractures (mother or sister)
    b. Weight <127 pounds or 58 kg or BMI <20 (ICSI)
    c. Alcoholism
    d. Current tobacco smoking
    e. History of premature menopause (prior to age 45)
    f. Frailty/high likelihood of falls
    g. Excessive caffeine intake
    h. Gonadal hormone deficiency
    i. Immobilization and inadequate activity
    j. Low calcium or vitamin D intake
    k. White or Asian race
5. Men aged 50-69 based on risk factor profile (NOF; but evidence is insufficient to access benefit/harm (USPSTF, See Table 5)

6. Adults (both women and men) who have a fracture (NOF) without major trauma (low-impact/fragility fracture)
7. Adults with significant acquired kyphosis and/or historical height loss >4 cm or measured height loss greater than 2 cm should have lateral vertebral assessment with DEXA or thoracic and lumbar spine radiographs and bone density testing (ICSI)
8. Consider in patients with fractures who are willing to accept treatment
9. Patients undergoing organ transplantation – recommend baseline BMD test at entrance to transplantation program, follow-up yearly prior to transplant (or every 6-12 months if on high-dose steroids), then yearly after transplant (ICSI)
10. May be recommended with exogenous (oral) glucocorticoid (ICSI) therapy (past, present, or ongoing) equivalent to prednisone 5 mg/day or more for 3 months. DEXA may be done at initiation of treatment if greater than 3-month course is anticipated.
11. May be recommended if peripheral screening is abnormal or inconclusive.
12. May be recommended medical conditions and medications associated with an increased risk of osteoporosis in adults (Appendix Tables 3 and 4)

Diagnosis via DEXA Scan Interpretation

Diagnosis is obtained by DEXA measurement of bone density at hip and lumbar spine. The resulting T-scores measure the number of standard deviations from the mean level for a young adult population. In pre-menopausal women and men <50 years, an ethnic or race-adjusted Z-score should be used for diagnosis. Diagnosis and decision to treat is further clarified by calculation of the FRAX score. (ICSI)

FRAX®; www.NOF.org and www.shef.ac.uk/FRAX

DEXA scores:

1. Normal: T-score ≥ -1, Z-score > -2.0
2. Low bone mass (osteopenia): T-score between -1 and -2.5
    i. Use FRAX to determine if treatment is indicated
3. Osteoporosis: T-score ≤ -2.5

In some patients it is reasonable to make a presumptive diagnosis and start treating despite absence of BMD assessment (ICSI)

Recommendations for Repeat Bone Mineral Density Scanning (Central DEXA)

Repeat DEXA scanning should ideally be performed at same testing center as original scan to improve accuracy of data. The frequency will depend upon the clinical situation. Generally repeat DEXA should be done no more than every 12-24 months (ICSI), may consider more often in steroid-treated patients or other high-risk individuals.

1. Baseline T scores > -1.0, no new risk factors: repeat in 5 - 10 years.
2. Baseline T scores < -1.0, not on therapy, with ongoing risk factors: repeat in 2-4 years.
3. Baseline T scores < -1.5, monitoring therapy: repeat in 5 years. (ACP)
4. Aggressive disease progression suspected, based on clinical situation: may repeat in 6-12 months, but this should be fairly uncommon.

Recommendations for Initiation of Therapy (Appendix Table 4)

Postmenopausal women and men age 50 and older presenting with the following should be considered for treatment:

1. A hip or vertebral (clinical or morphometric) fracture (fragility fracture)
2. T-score ≤ -2.5 at the femoral neck, lumbar spine (anteroposterior), or hip after appropriate evaluation to exclude secondary causes
3. Low bone mass: T-score between -1.0 and -2.5 at the femoral neck or 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 WHO absolute fracture risk model (FRAX)
    FRAX®; www.NOF.org and www.shef.ac.uk/FRAX
4. Steroid use at supra-physiologic doses anticipated for > 3 months duration
5. Consider all men and postmenopausal women with low-impact (fragility fractures) as potential candidates for pharmacologic intervention, even without bone density testing

Table 1: Recommended Pharmacological Agents for Osteoporosis (latest 11/2019)

Medication	Place in Therapy	Dose Administration	Reduction in fracture risk	Adverse drug reactions	Contraindications
Bisphosphonates *****Should be considered unless contraindication exist**					
Alendronate (Fosamax)	**First line** in majority of cases for osteoporosis treatment in men and women **Should be considered if no contraindication** Shown to increase BMD and reduce vertebral, hip, and non-vertebral fractures in postmenopausal women with existing vertebral fractures, and those with low BMD Increases BMD in patients who require long-term glucocorticoid therapy Preventive therapy for men undergoing androgen-deprivation tx for prostate cancer (ICSI)	70 mg tablet by mouth once weekly	Vert: +++ Nonvert: ++ Hip: +++	Common: • Abdominal pain • Dyspepsia • Diarrhea • Flu-like symptoms (rare postmarket experience) • Nausea • Constipation Serious: • Osteonecrosis of the jaw (ONJ) (rare) • Gastric ulcer • Esophageal ulcer • Esophagitis • Dysphagia • Atypical fractures	• Abnormalities of the esophagus that delay esophageal emptying • Inability to sit/stand for 30 minutes • Hypersensitivity • Uncorrected hypocalcemia • **CrCl ≤ 35 ml/min**
Zoledronic Acid (Reclast)	Approved for increasing BMD in men and postmenopausal women Preventative therapy after a hip fracture as well as once every 2 years for prevention of first fracture Should be considered in men undergoing androgen deprivation therapy for prostate cancer (ICSI) Supported for reducing bone loss in patients diagnosed with glucocorticoid-induced bone loss May prevent bone loss after organ transplantation	**TREATMENT:** A single 5mg infusion once a year given intravenously (IV) over no less than 15 minutes. **PREVENTION:** 5mg infusion given IV once every 2 years over no less than 15 minutes *Must adequately supplement calcium and vitamin D if dietary intake is not sufficient - average of at least 1,200 mg of calcium and 800 to 1,000 units of vitamin D daily is recommended *Make sure well-hydrated *Pre-treat with APAP to prevent acute phase reaction (NOF)	Vert: +++ Non-vert: ++ Hip: ++	**FDA warning 2011: CI in patients with renal impairment CrCl<35ml/min** • Acute phase reaction: fever, flu-like symptoms, HA, arthralgia/myalgia; (may pre-treat with APAP) • Jaw osteonecrosis (rare); recommend routine oral exam prior to initiation • Transient increase in creatinine • Atrial fibrillation • Hypocalcemia • Nausea/ vomiting/ diarrhea • Eye inflammation • Atypical femur fractures (rare) with long use (>5 years)	• Hypersensitivity • Uncorrected hypocalcemia • **CrCl < 35 ml/min**
RANK Ligand (RANKL) Inhibitor/ Human Monoclonal Antibody					
Denosumab (Prolia)	**Place in therapy:** Option for those at high risk of fracture Option for those with contraindications to bisphosphonates (renal function) Approved for men treated with androgen-	60 mg SQ once every 6 months, administered by a health professional Taken with calcium 1000 mg daily and at least 400 IU vitamin D daily *When stopped, bone loss is rapid; use another	Vert: +++, Non-vert: + Hip: ++	Common: • Hypertriglyceridemia • Vommitting • Anemia • Pain (back, extremity, and muscoskeletal) • Rash • Cystitis • Nasopharyngitis	• Hypersensitivity • Hypocalcemia (must correct prior to initiation) • Pregnancy

	deprivation therapy and women receiving adjunctive aromatase inhibitor therapy for breast cancer, and at high risk for fracture Must correct hypocalcemia and vitD deficiency prior to initiation	agent to maintain BMD		• URI • Fatigue Serious: • Endocarditis • Cellulitis • Dermatitis • Hypocalcemia • Anaphylaxis • Aseptic necrosis of the jaw (rare) • Atypical femoral fracture • Cancer	
Anabolic Agents: Parathyroid Hormone (PTH)					
Teriparatide (Forteo)	**Place in therapy:** Typically reserved for (women) with severe osteoporosis or who have had fractures (NOF) Generally not first line because lack of data on all fracture types (ACP) Studied in both men and postmenopausal women for treatment of osteoporosis and glucocorticoid-induced osteoporosis Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture	20mcg SubQ daily for not more than 2 years *Not to be used for more than 2 years *When stopped, bone loss is rapid; use another agent to maintain BMD	Vert: +++ Non-vert: +++ Hip: N/A	**BLACK BOXED WARNING:** **Show to cause an increase in the incidence of osteosarcoma in male and female rats, dependent on dose and duration of treatment.** • Orthostatic hypotension • Nausea • Increase in serum calcium • May increase risk of digoxin toxicity • Increase in urinary calcium • Arthralgia • Pain • Leg cramps	• Hypersensitivity • Avoid in patients with increased risk of osteosarcoma (including Paget's disease, prior radiation, unexplained elevation of alkaline phosphatase, or in patients with open epiphyses) • Do not use in patients with a history of skeletal metastases, hyperparathyroidism or pre-existing hypercalcemia • Not for use in patients with metabolic bone disease other than osteoporosis. • Should not be administered to pregnant or breastfeeding women
Medications for SELECT Patient Populations					
Selective Estrogen Receptor Modulator (SERM) Raloxifene	Approved for prevention and treatment of postmenopausal osteoporosis Option for women with an elevated risk of breast cancer		Vert: Non-vert: - Hip: -	**BLACK BOXED WARNING: Risk of deep vein thrombosis and pulmonary embolism** **Common:** • Hot sweats • Leg Cramp **Serious:** • VTE • Cerebrovascular accident **Thromboembolism**	• History of venous thromboembolism • Pregnant or nursing women
Female Menopausal Hormone Therapy: Estrogen +/- Progestin	NOT recommended first line in management or prevention of osteoporosis For women at significant risk who cannot take non-estrogen therapies	Strength and doses vary		**BLACK BOXED WARNING:** **Endometrial cancer, Cardiovascular disease, Breast Cancer, Dementia** Reactions depend on dose formulation • Cerebrovascular accident, edema, hypertension, MI, PE	• Undiagnosed abnormal genital bleeding • DVT or PE (current or history) • Active or recent arterial thromboembolic disease (stroke, MI) • Carcinoma of breast • Estrogen-dependent tumor • Hepatic dysfunction or disease • Pregnancy

				• Dementia exacerbation, depression, dizziness, headache, irritability • Pruritus, urticaria • Change in libido, hirsutism, weight changes, hypocalcemia • Abdominal cramps, nausea, vomiting	
Male Hormone Therapy: Testosterone	NOT FDA approved for osteoporosis, but may be and option for men symptomatic with hypogonadism Bone loss associated with male hypogonadism is reversed by testosterone therapy (partly via aromatization to estrogen) ONLY administered for hypogonadism caused by disorders of the testicles, pituitary gland or brain in adult males; not for treatment of low testosterone due to aging (ICSI)	Dose and administration vary by agent	N/A	**BLACK BOXED WARNING: Blood pressure increases (oral testosterone undecanoate; subQ testosterone enanthate** • Venous thromboembolic events Concerns on cardiovascular safety Reactions depend on dose and formulation • Skin reactions, pruritus • BPH, PSA increase • Increased hematocrit • Peripheral edema, vascular disease • Emotional lability, depression, anxiety, fatigue, • Acne vulgaris • Hyperlipidemia, decrease HDL, increased triglycerides, • Increase TSH, increased estradiol • Decreased libido, gynecomastia, hot flash, weight gain • Sleep apnea	• Breast cancer • Prostate cancer (known or suspected) • Pregnancy • Serious cardiac, hepatic, or renal disease
No longer recommended					
Calcitonin	**No longer recommended** FDA concludes that benefits **DO NOT** outweigh the risks Use should be limited to those with no possible alternatives Short-term use may provide analgesic effect for acute pain from a compression fracture	200 units (1 spray) in one nostril daily; alternate nostrils daily	Fracture reduction efficacy has not been demonstrated: agent not preferred	Common: • Rhinitis • Flushing, rash • Depression, dizziness, paresthesia • Nausea, abdominal pain • Infection • Back pain, myalgia, osteoarthritis • Conjunctivitis • Bronchospasm, flu-like symptoms, sinusitis, URI Concerns of cancer risk • Neoplasm • Lymphadenopathy	• Hypersensitivity reactions: Salmon-derived products • Hypocalcemia (correct prior to therapy)

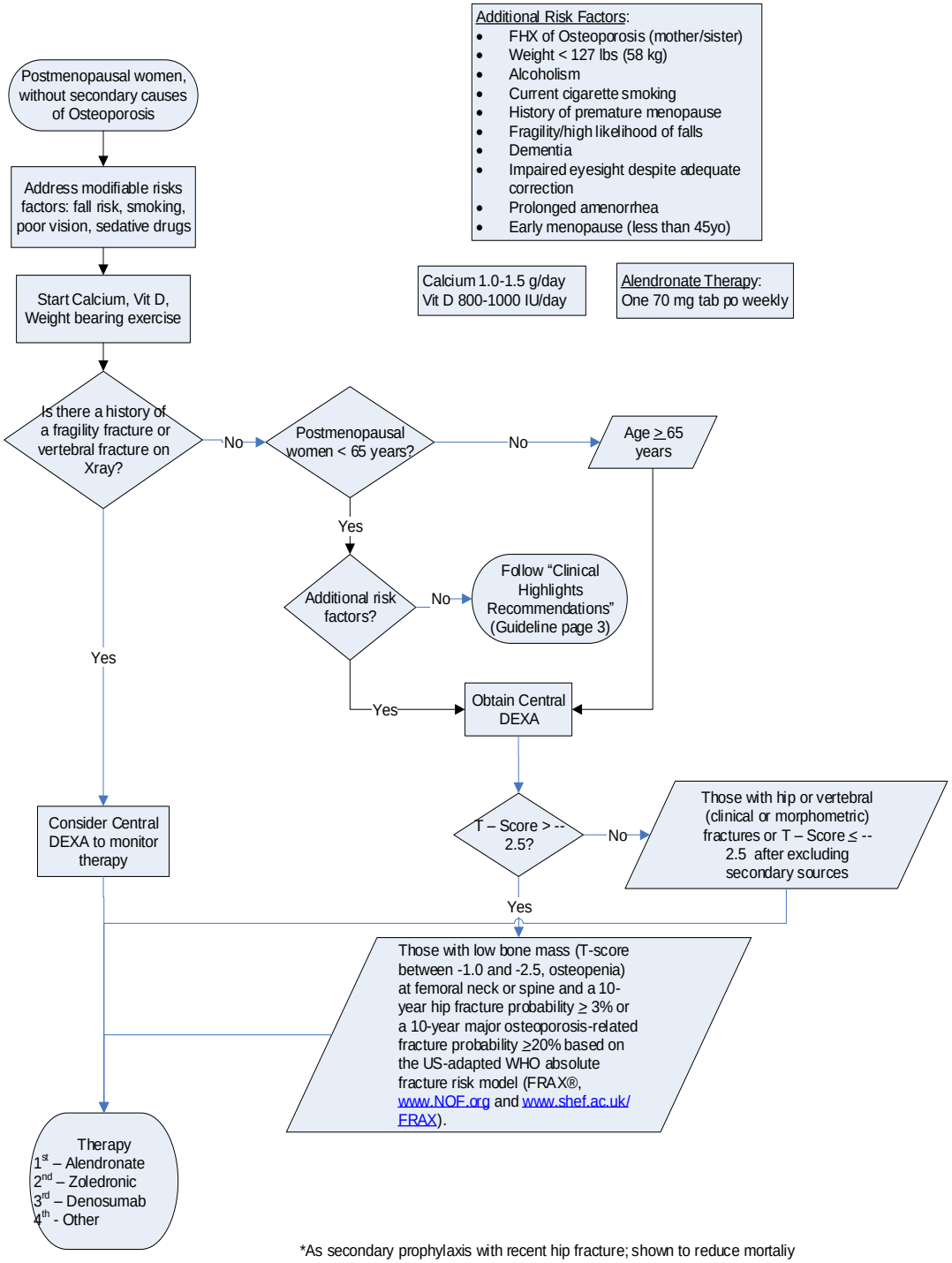
Vert = vertebral; nonvert = nonvertebral; +++ > 50% reduction; ++ 40-50% reduction; + < 40% reduction; - unable to show reduced risk; N/A No data available from RCT

Duration of Treatments

1. No pharmacologic treatment should be considered indefinite; duration decisions need to be individualized. (NOF)
2. Assuming renal function remains adequate, recommended bisphosphonate therapy duration is
    a. 5 years on alendronate in moderate-risk patients
    b. 6-10 years on alendronate in higher-risk patients
    c. 3 annual doses of IV zoledronic acid in moderate-risk patients
    d. 6 annual doses in higher-risk patients on IV zoledronic acid
    e. Benefits of bisphosphonates may continue after discontinuation (NOOG, NOF)
    f. May use teriparatide or denosumab during the “bisphosphonate holiday” period for higher-risk patients
3. Treatment with teriparatide should be limited to 2 years
    a. After stopping treatment, bone loss is rapid; treatment should be switched to another agent (NOF)
4. After stopping treatment with denosumab, bone loss is rapid (NOF)
    a. Ensure patient is dedicated to therapy and adherence
    b. Consider switching to another agent after discontinuation as bone loss is rapid

Appendix

Figure 1: Algorithm for Prevention, Screening, and Treatment in Postmenopausal Women



*As secondary prophylaxis with recent hip fracture; shown to reduce mortaliy

Table 2: Common Sources of Calcium and Vitamin D

***ALL patients should be encouraged to get adequate amounts of calcium and vitamin D first and foremost from their diet, and supplement only what is needed.**

	Dietary Sources *of Calcium*	**Dietary Sources of *Vitamin D***
Milk (Vitamin D fortified)	300 mg Ca per 8 oz serving	400 IU per quart
Yogurt (Vitamin D fortified)	400 mg Ca per 8 oz serving	~65 IU
Cheese	200 mg ***Ca*** per 1 oz serving	
Fortified foods or juices	80-1000 mg ***Ca*** per serving, as per label	(Vitamin D fortified cereal) ≥40-50 IU per serving
Alaska Native chum, raw	7mg ***Ca***/100grams (3.5ounces)	*Food sources of vitamin D are affected by the time of year they are harvested (ICSI)
Alaska Native red, smoked, canned	69mg ***Ca***/100grams (3.5ounces)	
Common Supplements available at ANMC		
Calcium carbonate1250 mg (Oscal)	500 mg elemental calcium per tab	
Combination Calcium and vitamin D (Oyster Shell Calcium with Vitamin D)	500 mg elemental calcium plus 200 International Units vitamin D per tab	
Vitamin D3 (cholecalciferal)	1,000 IU tablet	
Vitamin D3 (cholecalciferal)	5,000 IU capsule	
Vitamin D2 (ergocalciferal)	50,000 IU capsule	

**Example: One tablet of Oyster shell Calcium with Vitamin D BID would provide 1000 mg calcium plus 400 IU vitamin D, appropriate for those who consume very little dairy or other calcium-rich food. One tablet daily would be appropriate for a person consuming two calcium-rich foods/day.

Table 3: Medications Associated with an Increased Risk of Osteoporosis in Adults

• Aluminum • Anticonvulsants • Aromatase inhibitors • Barbiturates • Caffeine (in excess) • Chemotherapeutic drugs • Cyclosporine A • Diuretics causing hypercalciuria • Glucocorticosteroids ≥ 5mg/day of prednisone or equivalent for ≥3 months	• Gonadotropin-releasing hormone agonists • Heparin (long-term) • Lithium • Methotrexate • Phenazothiazine derivatives • Pioglitazone and rosiglitazone • Proton Pump Inhibitors • Provera depo (chronic) • SSRIs	• Tacrolimus • Tamoxifen (premenopausal) • Thyroid hormone (supra-therapeutic) • Tenofovir • Tetracycline (extended use) • Total Parenteral Nutrition • Vitamin A (excess) • Warfarin (long term)

Table 4. Osteoporosis Screening Recommendations of Other Organizations

	Recommendations	
Organization	**Women**	**Men**
National Osteoporosis Foundation (NOF 2014)	BMD testing for all women ≥65 y and postmenopausal women <65 y, based on risk factor profile	BMD testing for all men ≥70 y and men aged 50-69 y, based on risk factor profile
	BMD testing in all adults (women and men) who have a fracture after age 50 and adults with a condition or taking a medication associated with low bone mass or bone loss	
World Health Organization (WHO)	Indirect evidence supports screening women ≥65 y, but no direct evidence supports widespread screening programs using BMD testing	
American College of Physicians on Screening for Men (ACP 2008)		Clinicians should assess older men for osteoporosis risk factors and use DEXA to screen men at increased risk who are candidates for drug therapy for osteoporosis
American Congress of Obstetricians and Gynecologists (ACOG 2012)	BMD testing for all women ≥65 y and postmenopausal women <65 y who have 1 or more risk factors	
U.S. Preventive Services Task Force (USPSTF 2018)	All women aged ≥ 65 years and younger women whose 10-year fracture risk is equal to or greater than that of a 65-year-old Caucasian woman with no additional risk factors (using FRAX algorithm)	No recommendation. Current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis in men.
American Association of Clinical Endocrinologists (AACE 2016)	Evaluate all postmenopausal women ≥50 years for risk through detailed history, physical exam, FRAX tool. Consider BMD testing based on clinical fracture risk profile	
North American Menopause Society (NAMS 2014)	BMD testing recommended for all women ≥65 years, with consideration for earlier testing in women with clinical risk factors for fracture (low body weight, history of prior fracture, family history of osteoporosis, smoking, excessive alcohol intake, or long-term use of high-risk medications)	N/A
Endocrine Society (on osteoporosis in men)		BMD in men at increased risk – age 70 is a sufficient risk factor. Younger

(2011)		men 50-69 years should be tested if additional risk factors are present

BMD = bone mineral density; DEXA = dual-energy x-ray absorptiometry

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