

Prevention & Treatment of Osteoporosis in Women: Synopsis – 2004 *(see supporting document for more detailed information)*

At HVMA, data on bone mineral density measurement suggest that we are inadequately screening the high risk population and missing opportunities for appropriate intervention with therapy. On the other hand, we may be over treating a population for whom the role of medications is unclear (e.g. , women with osteopenia without significant risk for fracture).

Clinical Recommendations For All Women ≥ 50 year of age: *(See EpicCare desktop for patient education materials)*

- Take 400-800 IU of Vitamin D daily (from MVI or in combination Ca⁺⁺ - see medication chart). Sunlight and food may not be adequate as source of vitamin D, especially in the northeast.
- Take 1200-1500 mg (max. 2500 mg) of elemental calcium in divided doses daily (from food or Ca⁺⁺ supplements – see medication chart).
- Avoid tobacco and excess alcohol.
- Do regular weight-bearing exercise (e.g., brisk walking, jogging, aerobics, jumping rope, stair climbing, and tennis).
- Pursue fall prevention (e.g., correct vision & hearing, evaluate neurological problems, review medications that may affect balance and stability, and provide a check list for home safety).

Who to Screen (using preferred screening method - DEXA BMD testing):

- All women ≥ 65 years old regardless of risk factors.
- Women age 60-64 with high risk of fracture (specifically personal history of fracture after age 20, first degree relative with fragility* fracture, smoking, weight<154 lbs, not on hormone replacement therapy, or x-ray evidence of low bone mass).
- Only women in the above categories who are willing to modify health behaviors and/or use medications that lower the risk for osteoporotic fracture based on the test results.
- Patients (male or female) with a history of a fragility* fracture.
- Patients (male or female) ≥18 year of age who are on chronic corticosteroids (e.g., > 3 month with dose equivalent to ≥ prednisone 5mg/day or > 6weeks with dose equivalent to ≥ prednisone 7.5mg/day). Some experts recommend initiating pharmacotherapy regardless of BMD.

*Fragility fracture is one that results from a fall from a level surface while standing or walking, from a fall from less than standing height (such as from a chair), or from a force that would not ordinarily cause fracture in a healthy young adult (such as from coughing or bending).

Who NOT to Screen:

- Pre-menopausal women without significant risk factors (e.g., steroids, hypoestrogenic amenorrhea.)
- There is considerable pressure to screen peri and postmenopausal women under age 60. However, there are inadequate data to support the routine practice of screening this age group. Individual decisions to screen this population should be based on significant risk for fracture in addition to being postmenopausal.

Interpreting Screening BMD Results & Monitoring Therapeutic Response

T score: <i>comparison to healthy, 30 year old women. Use lowest T score to make diagnosis and treatment decisions.</i>		What to do <i>To establish the optimal interval for BMD repeat screening, consider using the “Bone Loss Calculator” under Bone Densitometry calculators at http://www.iscd.org/Visitors/xls/BoneLossCalculator.xls to assess the potential rate of bone loss.</i>
≥ -1 SD	Normal	no need to re-screen for 5 years unless change in medical status such as new fracture, starting steroids, or significant weight loss; emphasize use of calcium, vitamin D, & exercise.
-1 to -1.5 SD	Osteopenia	pharmacologic treatment not indicated, repeat BMD in 2-3 years; emphasize use of calcium, vitamin D, & exercise.
-1.5 to -2 SD		no evidence that pharmacologic treatment prevents fracture in this population; emphasize use of calcium, vitamin D, & exercise – repeat BMD in 2 years.
-2 to -2.5 SD		pharmacologic therapy may benefit although no clear trial data showing fracture prevention; emphasize use of calcium, vitamin D, & exercise in this population. The decision to treat should be individualized. If medication is initiated, repeat BMD in 2 years. For those not on medication, repeat BMD in 1-2 years.
≤ -2.5 SD	Osteoporosis	treat with medication; emphasize use of calcium, vitamin D, & exercise. Repeat BMD in 2 years.
Z score: <i>comparison to peer group. Use Z score to make decision about secondary work-up.</i>		Z score ≤ -2 should trigger evaluation for possible secondary causes, including hyperparathyroidism, hyperthyroidism, renal disease, low vitamin D, and other systemic medical risks for osteoporosis.

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Medications for Osteoporosis Prevention & Treatment – 2004

Over-the-Counter Ca ⁺⁺ Supplements* (most available as generics)	mg of elemental Ca ⁺⁺	Vitamin D if present (IU)	Approx. \$
Tums, Tums EX, Tums Ultra (Ca ⁺⁺ Carbonate)	200 mg, 300 mg, 400 mg	N/A	\$5.00/150
Oscal (Ca ⁺⁺ Carbonate)	500 mg	N/A	\$3.00/120 (generic), \$15.00/160 (brand)
Viactiv Chewable (Ca ⁺⁺ Carbonate)	500 mg	100 IU	\$8.00/60
Caltrate 600 Plus (Ca ⁺⁺ Carbonate)	600 mg	200 IU	\$8.00/60
Citracal (Ca ⁺⁺ Citrate products)	200 mg	N/A	\$15.00/200
Citracal + D (Ca ⁺⁺ Citrate products)	315 mg	200 IU	\$9.00/60

* Ca⁺⁺ supplement should be taken in divided doses since no more than 500 mg of elemental Ca⁺⁺ can be absorbed at once. Calcium carbonate products should be taken with food.

	Prevention	Treatment	Clinical Notes	HPhC/ NHPcom	Tuft HP	BCBSMA	NHPMH*
Bisphosphonate							
Alendronate (Fosamax®)	35 mg po qwk	70 mg po qwk	Decrease hip and spine fractures as much as 50% in women with osteoporosis. Side effect: esophageal irritation. Instruct patient to take medication with 6-8 oz of water, at least 30 min. before first food and drink, and to remain upright at least 30 minutes.	T2	T2	T2, QL	Brand
Risedronate (Actonel®)	35 mg po qwk	35 mg po qwk		T3	T3	T2, QL	Brand
Selective Estrogen Receptor Modulators (SERMs)							
Raloxifene (Evista®)	60 mg po qd	60 mg po qd	Decreases spine but not yet shown to decrease hip fractures , may offer some protection against breast CA in high risk women. Increases risk of thrombosis, worsens symptoms of hot flashes in 10-25% of women.	T2	T2	T2	Brand
Estrogen Replacement (example)							
Estradiol, micronized (Estrace®) (Estrace® is tier 1 for all payors and most cost-effective for HVMA. Other estrogen products are available but may not be covered as tier 1 for all payors)	0.5 – 2 mg po qd	Not indicated	The Women's Health Initiative studied mostly older women (avg. age 63) on <i>Prempro</i> . The incidence of fractures declined, but the risk of breast cancer, coronary events, stroke, and venous thrombosis was increased in those taking Prempro. Although the implications for younger women who are closer to the onset of menopause and those who are on other estrogen preparations are uncertain, estrogen is generally not recommended solely for the prevention of osteoporotic fractures. However, for patients using estrogen for other indications, additional medication for osteoporosis may not be needed.	T1	T1	T1	Generic
Consider Cenestin® for patients requiring a conjugated estrogen.	0.625 mg po qd	Not indicated		T2	T3	NC	Brand
Polypeptide Hormone							
Calcitonin (Miacalcin- Nasal®)	Not indicated	200 IU intranasally qd	Not very effective, should only be used when intolerant to all other available options. Approved for women 5 years postmenopausal , decreases spine but not hip fractures , no clear dose response, side effects include dry nasal passages and epistaxis.	T2	T2	T2	Brand
Parathyroid Hormone							
Teriparatide (Forteo®)	Not indicated	20 mcg SC qd	Expensive (appro. \$6,000 per patient per year), increased incidence of osteosarcoma in animal studies, should be limited to patients seen in Endocrinology	T3, PA (HPhC only)	T2, PA	T2, PA	Brand

*NHPMassHealth – generic copay=\$1.00, brand copay=\$2.00; T1=Tier 1, T2=Tier 2, T3=Tier 3, NC=Not covered, OTC=over-the-counter, QL= quantity limit, PA = Prior Authorization

For off label use of other medications (e.g., pamidronate, etidronate), consult with Endocrinology or Menopause Consultation Service.

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