

Osteoporosis Guideline

These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients. They are not intended to replace a clinician’s judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.

GUIDELINE HISTORY and APPROVAL

ACTION	SEED GUIDELINE and/or MAIN INFORMATION & GROUP SOURCE(S)	DATE	ORGANIZATION
Guideline reviewed, revised and approved	National Osteoporosis Foundation, American Association of Clinical Endocrinologists, and the American College of Rheumatology	April 26, 2000	Geisinger Health Plan/ Quality Improvement Committee
Guideline reviewed, revised and approved	Same as above	June 12-July 11, 2001	Osteoporosis Guideline Team
Guideline reviewed, revised and approved	Same as above	July 11-12, 2001	Geisinger Health Plan/ clinical Guideline Committee
Guideline reviewed, revised and approved	Same as above	July 25, 2001	Geisinger Health Plan/ Quality Improvement Committee
Guideline reviewed, revised and approved	Same as above	July 26 – Oct 1, 2001	Osteoporosis Guideline Team
Guideline reviewed, revised and approved	Same as above	June 5, 2002	Geisinger Health Plan/ Clinical Guideline Committee
Guideline reviewed, revised and approved	Same as above	July 24, 2002	Geisinger Health Plan/ Quality Improvement Committee
Guideline reviewed, revised and approved	Same as above	June 1-15, 2003	Osteoporosis Guideline Team
Guideline reviewed, revised and approved	Same as above	March 11, 2004	Geisinger Health plan Guideline Review Conference/Osteoporosis Team members
Guideline reviewed, revised and approved	Same as above	March 12 – April 2004	Geisinger Health Plan/ Clinical Guideline Committee
Guideline reviewed, revised and approved	Same as above	April 28, 2004	Geisinger Health Plan/ Quality Improvement Committee
Guideline reviewed, revised and approved	Same as above	May 5, 2004	Geisinger Health Plan/ Medical Management Committee (MMC)
Guideline reviewed, revised and approved	Same as above	Sept. 12, 2005	Geisinger Health Plan/ Clinical Guideline Committee
Guideline reviewed, revised and approved	Same as above	Sept. 14, 2005	Geisinger Health Plan/Pharmacy
Guideline reviewed, revised and approved	Same as above	Sept. 19-30, 2005	Geisinger Health Plan/ Medical Directors

Osteoporosis Guideline

Guideline reviewed, revised and approved	Same as above, American Association of Clinical Endocrinologists: AACE Medical guidelines for clinical practice for the prevention and management of postmenopausal osteoporosis: with selected updates for 2003. Surgeon General's Report: Bone Health and Osteoporosis: A report of the Surgeon General.	Aug. 24 – Oct. 10, 2005	Geisinger Medical Center Osteoporosis Guidelines Group
Guideline reviewed, revised and approved	Same as above	Dec. 5, 2005	Geisinger Health Plan/ Medical Management Committee (MMC)
Guideline reviewed, revised and approved	Same as above	Jan. 25, 2006	Geisinger Health Plan/ Quality Improvement Committee
Guideline revised and approved	Same as above	July 26, 2006	Geisinger Health Plan/ Quality Improvement Committee
Guideline revised and approved	Same as above	July 16, 2007	Geisinger Health Plan/ Clinical Guideline Committee
Guideline revised and approved	Same as above	July 19, 2007	Geisinger Health Plan/ Pharmacy
Guideline revised and approved	Same as above	Dec. 5-14	Geisinger Health Plan/ Medical Directors
Guideline revised and approved	Same as above	Dec. 17, 2007	Geisinger Health Plan/ Medical Management Committee (MMC)
Guideline revised and approved	Same as above	Jan. 23, 2008	Geisinger Health Plan/ Quality Improvement Committee



Duane E. Davis, M.D.
Vice President, Chief Medical Officer
Geisinger Health Plan

OVERVIEW

Scope Of The Problem

Osteoporosis, or porous bone, is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures, especially of the hip, spine and wrist, although any bone can be affected.

Osteoporosis is a major public health threat for an estimated 44 million Americans, or 55 percent of the people 50 years of age and older. In the U.S., 10 million individuals are estimated to already have the disease and almost 34 million more are estimated to have low bone mass, placing them at increased risk for osteoporosis. Of the 10 million Americans estimated to have osteoporosis, eight million are women and two million are men.

Medical Impact

One in two women and one in four men over age 50 will have an osteoporosis-related fracture in her/his remaining lifetime.

Osteoporosis is responsible for more than 1.5 million fractures annually, including:

- over 300,000 hip fractures; and approximately
- 700,000 vertebral fractures;
- 250,000 wrist fractures; and
- 300,000 fractures at other sites.

In 2001, about 315,000 Americans age 45 and over were admitted to hospitals with hip fractures. Osteoporosis was the underlying cause of most of these injuries.

An average of 24 percent of hip fracture patients aged 50 and over die in the year following their fracture.

One in five of those who were ambulatory before their hip fracture requires long-term care afterward.

At six months after a hip fracture, only 15 percent of hip fracture patients can walk across a room unaided.

Not just hip fractures, but vertebral fractures are also linked with an increased risk of death.

One in five hip fracture patients ends up in a nursing home.

Economic Toll

The estimated national direct care expenditures (including hospitals, nursing homes, and outpatient services) for osteoporotic fractures is \$18 billion per year in 2002 dollars, and costs are rising.

There has been a five-fold increase in office visits for osteoporosis (from 1.3 to 6.3 million) in the past 10 years.

This overview is from the National Osteoporosis Foundation website located at:
<http://www.nof.org/osteoporosis/diseasefacts.htm>

SEED GUIDELINE

This edition of the Osteoporosis Clinical Practice Guideline is a compilation of evidenced-based science, expert opinion, and experience based on recommendations from the National Osteoporosis Foundation, the American Association of Clinical Endocrinologists, the American College of Rheumatology, and the National Institute of Health.

GOALS

Minimize the morbidity and mortality of Members with osteoporosis while achieving the highest quality of life. This is accomplished through:

1. Incorporation of the Osteoporosis clinical guideline into a comprehensive disease management approach;
2. Promotion of provider education related to the prevention, diagnosis, and treatment of osteoporosis.
3. Promotion of member self-management related to healthy lifestyle choices and medication management of osteoporosis.
4. Proper diagnosis and treatment of osteoporosis in post-menopausal women, elderly men, and patients receiving glucocorticoids.
5. Promotion of bone density testing in patients with risk factors for osteoporosis.
6. Promotion of bone density testing and/or medication management in patients that fracture due to osteoporosis.
7. Reduction in the incidence of fractures related to osteoporosis.

FAST FACTS

1. Osteoporotic fractures are a source of significant morbidity and mortality.
2. One in two women and one in four men over age 50 will have an osteoporosis-related fracture in their lifetime.
3. Osteoporosis can strike at any age.
4. Osteoporosis/fracture prevention involves healthy lifestyle changes (weight bearing exercise, smoking cessation, and proper calcium intake) and fall risk reduction (treating gait problems, use of supportive devices, home safety evaluation).
5. Testing of bone mineral density, using any device is the best predictor of fracture.
6. Bone density testing (DXA of hip/spine, heel ultrasound) in general should be offered to all postmenopausal women.
7. Consider risk factors that indicate higher risk for osteoporosis – chronic steroid therapy, previous fracture, age over 65 for women or 70 for men, history of osteoporotic fracture in first-degree relative, tobacco abuse and low body weight are several key risks.
8. Several treatment options are now available. See the clinical guidelines for further recommendations.

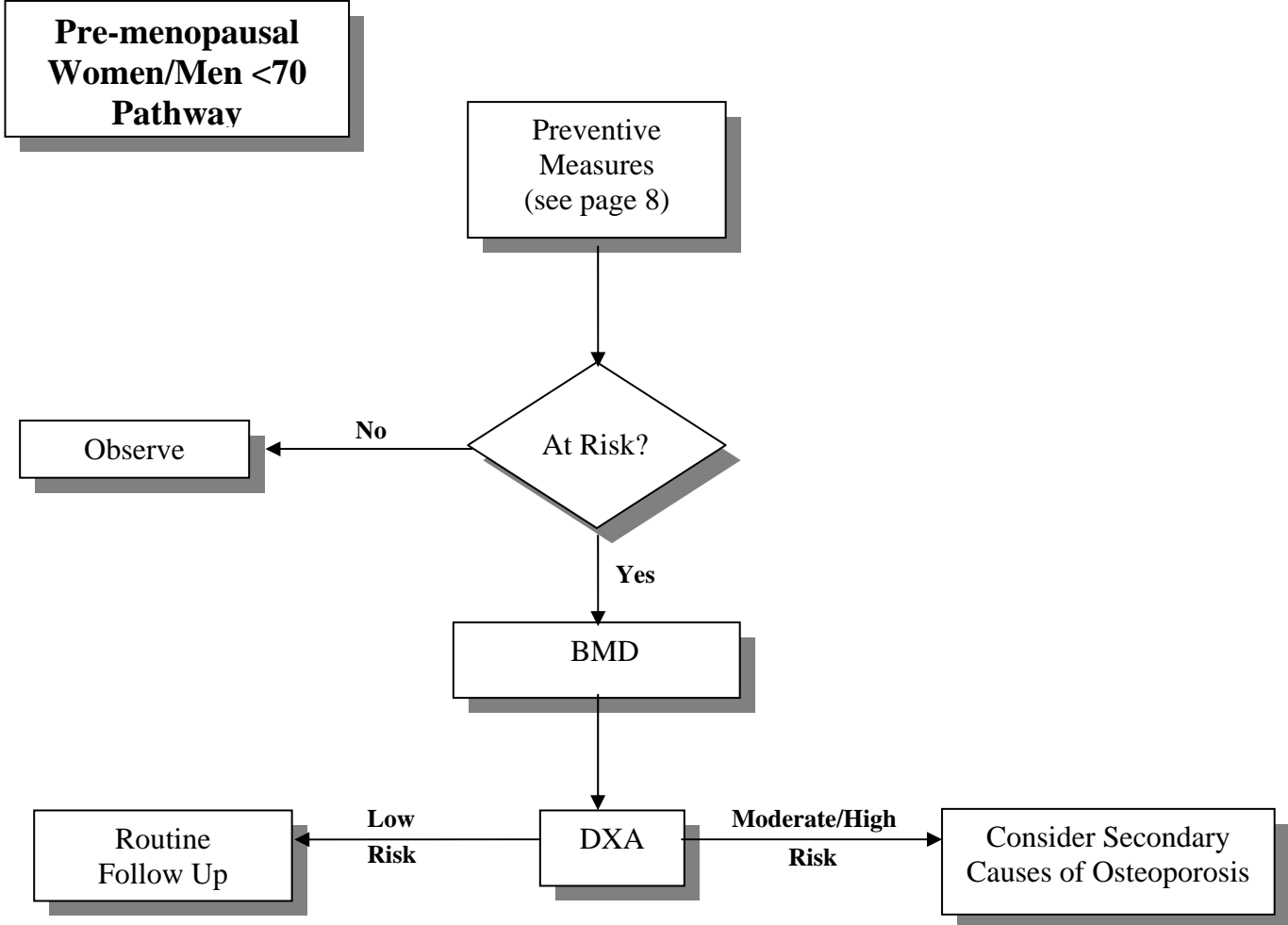
ALGORITHM

The Osteoporosis Clinical Guideline has five algorithms:

1. Pre-menopausal Women & Men < 70 Years Old Pathway
2. Postmenopausal Women Pathway.
3. Elderly Men > 70 Years Old Pathway
4. Chronic Steroid Pathway.
5. Fracture Pathway.

These algorithms can be found on-line at:

<http://www.geisinger.org/services/osteo/algos/guidelines.shtml> and at
<http://www.thehealthplan.com/>



Preventive Measures

A. Lifestyle Changes

1. Weight Bearing Exercises performed for 20-30 minutes 3-5 times per week (Examples include walking, jogging, dancing, bicycling)
2. Smoking cessation (tobacco is considered a major risk factor)
3. Dietary or supplemental changes to consume an adequate amount of calcium (1000 mg per day) and vitamin D (800 IU).
4. Make the patient's environment safer (good lighting, handrails, bathroom safety, avoid slippery surfaces and throw rugs)
5. Avoid high risk behaviors (Example: climbing ladders)

B. Identify, Modify and Treat certain medical situations

1. Address Musculoskeletal, Neurological, and Sensory problems, which interfere with balance and increase the propensity to fall (Examples include usage of canes, walkers, hearing aids, etc.)
2. Avoid sedating medications
3. Adjust thyroid medications to prevent over replacement

At Risk Patients Include:

- A. Demineralization on previous radiographs
- B. Spontaneous non-traumatic fractures
- C. Documented loss of height > 1 inch
- D. Chronic steroid use (> 7.5 mg/day for > 3 months or >5 mg/day for > 6 months) – see steroid algorithm
- E. Premature menopause (natural or surgical)
- F. Amenorrhea or sex hormone deficiency (e.g. athletes, eating disorders)
- G. Asymptomatic primary hyperparathyroidism
- H. Chronic diseases (e.g. rheumatoid arthritis, liver, renal, malabsorption)
- I. Medications (especially thyroid, anticonvulsant, anticoagulant)
- J. Excessive alcohol consumption
- K. Men with prostate cancer who are on hormone therapy
- L. Women with breast cancer, whose treatment includes hormonal ablation (causing surgical menopause) or those treated with aromatase inhibitors.

BMD (bone mineral density) Testing

- A. Bone density testing gives the best prediction of future fracture risk. It is more predictive of fracture risk than cholesterol measurement is a predictor of MI.
- B. DXA hip/spine
 1. Considered the “gold standard”
 2. Can be used in men and women
 3. Is very useful in monitoring BMD during treatment
 4. Is the preferred test in men and premenopausal women who require BMD testing

DXA Scan

- A. Best study for diagnosis and monitoring serially
- B. Interpreted in 3 risk categories
 1. Low Risk (T score is above -1.0): A repeat study can be performed in 3-5 years
 2. High Risk (T score is below -2.0 or below -1.5 with a major risk factor): Prescription treatment is suggested in this situation. Repeat study in 2-3 years.
 3. Moderate risk (T score is between the above two levels): No Prescription treatment is suggested but repeat DXA should be considered in 2-3 years.

Secondary Causes of Osteoporosis

- A. Z-score and secondary causes of osteoporosis
 1. The Z-score compares the person to an age/sex matched group
 2. If the Z-score is low (below -1.0) or very low (below -2.0), then the person's BMD is much lower than others their age. This raises the concern about secondary causes of osteoporosis.
 3. If secondary causes are a concern, basic lab work may include CBC, calcium, bun, creatinine, alk. phos., phosphorus, TSH, ESR, PTH, 25-OH Vitamin D, and total testosterone level. Other tests or referrals may need to be considered as clinically appropriate or as suggested by disease.
- B. There may be other clinical scenarios (such as non-traumatic fracture at an early age) that warrant consideration of secondary causes of osteoporosis.

Common Secondary Causes of Osteoporosis Include:**Endocrine/Metabolic**

- Hyperparathyroidism
- Hypogonadism
- Thyrotoxicosis
- Diabetes Mellitus, Type I

Nutritional

- Alcoholism
- Malabsorption diseases
- Anorexia Nervosa
- Malnutrition
- Celiac Disease
- Vitamin D deficiency

Drugs

- Anticonvulsant therapy
- Excessive thyroid medication
- Glucocorticoids

Other

Rheumatoid arthritis

Uncommon Secondary Causes of Osteoporosis Include:

Endocrine/Metabolic

- Acromegaly
- Hyperadrenocorticism
- Hyperprolactinemia
- Hypophosphatasia in adults
- Porphyria
- Pregnancy
- Systemic mastocytosis
- Thalassemia

Nutritional

- Chronic liver disease
- Gastric operations
- Calcium deficiency

Drugs

- Chronic heparin therapy

Collagen Metabolism

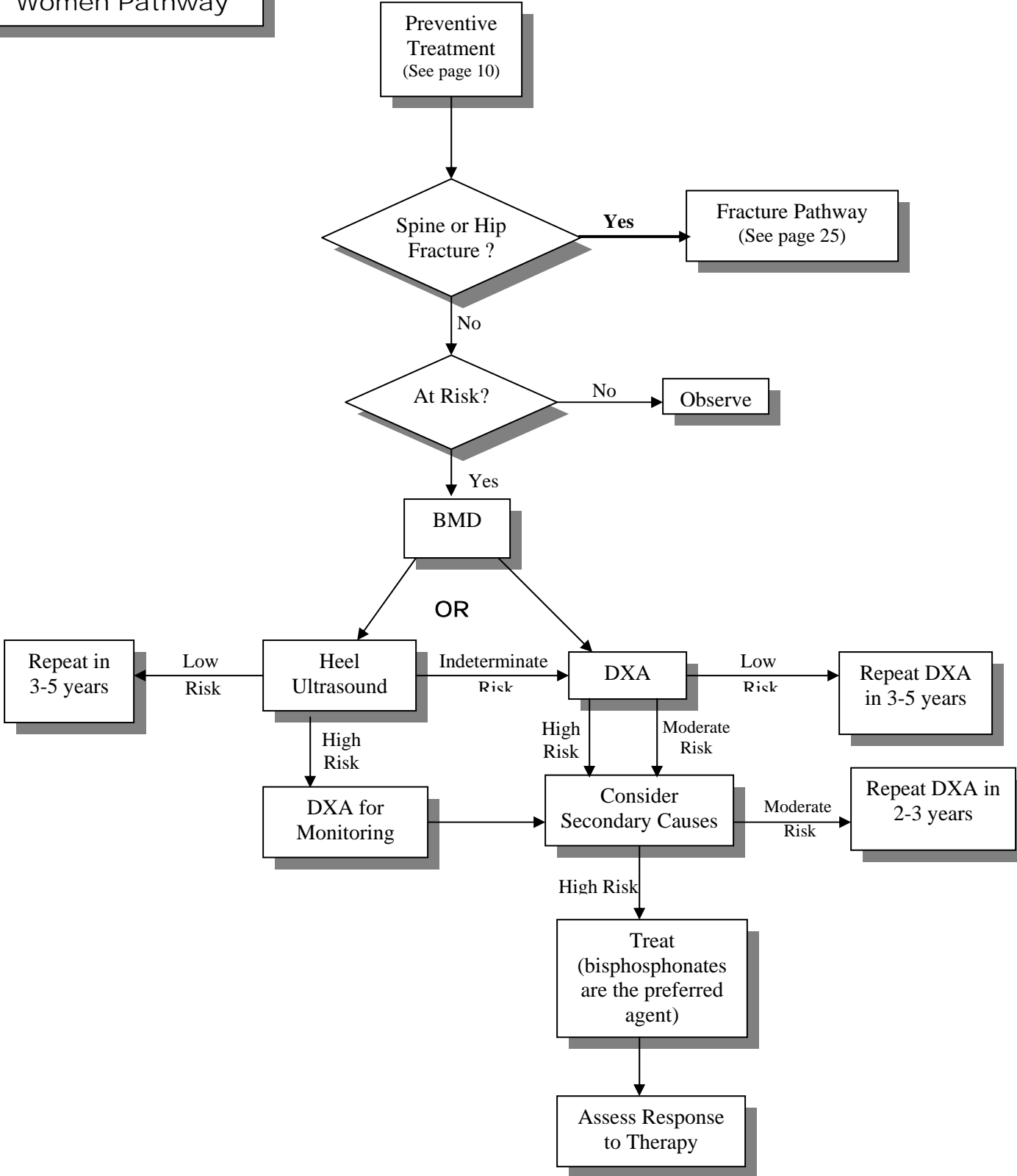
- Ehlers-Danlos syndrome
- Homocystinuria due to cystathione deficiency
- Marfan syndrome
- Osteogenesis imperfecta

Other

- Down's syndrome
- Immobilization (including spinal cord injuries)
- Renal tubular acidosis
- Myeloma and some cancers
- Hypercalciuria

Modified from the AACE Medical Guidelines for clinical practice for the prevention and management of postmenopausal osteoporosis: with selected updates for 2003. Endocrine Practice 2003;9(6):544-564.

Post-menopausal Women Pathway



Prevention

A. Lifestyle Changes

1. Weight Bearing Exercises performed for 20-30 minutes 3-5 times per week (Examples include walking, jogging, dancing, bicycling)
2. Smoking cessation (tobacco is considered a major risk factor)
3. Dietary changes to consume an adequate amount of calcium and vitamin D (dietary or supplemental): 1200-1500mg of calcium and 800 IU Vitamin D daily
4. Make the patient's environment safer (good lighting, avoid slippery surfaces/carpeting, handrails, bathroom safety)
5. Avoid high risk behaviors (Example: climbing ladders, avoid slippery surfaces)
6. Consider hip protectors in the elderly, frail nursing home population

B. Identify, Modify and Treat certain medical situations

1. Address Musculoskeletal, Neurological, and Sensory problems, which interfere with balance and increase the propensity to fall (Examples include usage of canes, walkers, hearing aids, etc.)
2. Avoid sedating medications
3. Adjust thyroid medications to prevent over replacement

Spine or Hip Fracture

- A. Defined as a fracture of the spine or hip not related to major trauma.
- B. Vertebral fracture may be suspected because of pain or height loss, and confirmed by radiographs.

At Risk Patients Include:

- A. Personal history of fragility fracture
- B. Age > 65 (Better test in this age group is DXA) (DXA is covered by Medicare and Medicare HMO health plans)
- C. Age < 65 plus a major risk factor (Insurance coverage is variable)
 1. Low Body Weight (<127 pounds)
 2. Current smoker
 3. Family History of osteoporotic fracture
- D. Age is < 65 and the results of the study will change potential therapy (Insurance coverage is variable)
- E. Hormone Therapy for > 5 years.
- F. Chronic Steroid Therapy (see Steroid Algorithm)
- G. Women with breast cancer, whose treatment includes hormonal ablation (causing surgical menopause) or those treated with aromatase inhibitors.

BMD (bone mineral density) Testing

- A. Bone density testing gives the best prediction of future fracture risk. It is more predictive of fracture risk than cholesterol measurement is a predictor of MI.

- B. The better reports of BMD use clinical data obtained from the patient and interpret the studies based upon National Osteoporosis Foundation Guidelines for diagnosis, treatment, and monitoring suggestions.
- C. Choices include:
 - 1. DXA hip/spine
 - a. Considered the “gold standard”
 - b. The definitive study for postmenopausal women
 - c. Can be used in men and women
 - d. Is very useful in monitoring BMD during treatment
 - e. Vertebral fracture assessment (VFA) can be performed at the same time as DXA in at risk populations (per protocol).
 - 2. Heel Ultrasound
 - a. Portable, simple, and economical to use as a screening study, especially in the postmenopausal woman < 65 years old
 - b. Do not use in men or premenopausal women
 - c. Do not use to monitor BMD serially

Heel Ultrasound

- A. A measurement which has 3 potential outcomes
 - 1. Normal BMD or Low Risk (T score is above 0.0): This is generally a good screen that the BMD is normal. A repeat study can then be performed in 3-5 years.
 - 2. Abnormal BMD or High Risk (T score is below -2.0 or below -1.5 with a major risk factor). This is felt to be an abnormal study and treatment is suggested. If the physician wants to monitor treatment, a DXA should be done so that serial studies can be properly interpreted.
 - 3. Indeterminate or Unknown Risk (Any value between normal and abnormal BMD): In this situation, a DXA scan is recommended for best accuracy in diagnosis.

DXA Scan

- A. Best study for diagnosis and monitoring serially
- B. Interpreted in 3 risk categories
 - 1. Low Risk (T score is above -1.0): A repeat study can be performed in 3-5 years
 - 2. High Risk (T score is below -2.0 or below -1.5 with a major risk factor, or nontraumatic hip or spine fracture): Prescription treatment is suggested in this situation. Repeat study in 2-3 years.
 - 3. Moderate risk (T score is between the above two levels): No Prescription treatment is suggested but repeat DXA should be considered in 2-3 years.

Secondary Causes of Osteoporosis

- A. Z-score and secondary causes of osteoporosis
 - 1. The Z-score compares the person to an age/sex matched group

2. If the Z-score is low (below -1.0) or very low (below -2.0), then the person's BMD is much lower than others their age. This raises the concern about secondary causes of osteoporosis.
 3. If secondary causes are a concern, basic lab work may include: 25-OH Vitamin D, CBC, comprehensive metabolic panel, phosphorus, TSH, PTH, and ESR (or immunoelectrophoresis and quantitative immunoglobulins if there is a suspicion for myeloma). For EPIC providers, use Osteoporosis Smart Set [1146]. Other tests or referrals may need to be considered as clinically appropriate or as suggested by disease.
- B. There may be other clinical scenarios (such as non-traumatic fracture at an early age) that warrant consideration of secondary causes of osteoporosis.

Common Secondary Causes of Osteoporosis Include:

Endocrine/Metabolic

- Hyperparathyroidism
- Thyrotoxicosis

Nutritional

- Alcoholism
- Calcium deficiency
- Malnutrition
- Vitamin D deficiency
- Celiac disease

Drugs

- Anticonvulsant therapy
- Excessive thyroid medication
- Glucocorticoids

Other

- Hypercalciuria
- Myeloma and some cancers
- Rheumatoid arthritis

Uncommon Secondary Causes of Osteoporosis Include:

Endocrine/Metabolic

- Acromegaly
- Diabetes Mellitus, Type I
- Hyperadrenocorticism
- Hyperprolactinemia
- Hypophosphatasia in adults
- Porphyria
- Systemic mastocytosis
- Thalassemia

Nutritional

- Anorexia Nervosa
- Chronic liver disease
- Gastric operations
- Malabsorption syndromes

Drugs

- Chronic heparin therapy

Collagen Metabolism

- Ehlers-Danlos syndrome
- Homocystinuria due to cystathione deficiency
- Marfan syndrome
- Osteogenesis imperfecta

Other

- Down's syndrome
- Immobilization (including spinal cord injuries)
- Renal tubular acidosis

Modified from the AACE Medical Guidelines for clinical practice for the prevention and management of postmenopausal osteoporosis: with selected updates for 2003. *Endocrine Practice* 2003;9(6):544-564.

Treatment Note: Pharmaceutical coverage is dependent upon individual pharmacy benefit design and certain drugs may require prior authorization. Providers are encouraged to review the GHP Formulary at <http://www.thehealthplan.com/>, or contact the GHP Pharmacy at 1-800-988-4861.

- A. All patients follow the prevention guidelines noted above. Appropriate calcium and Vitamin D supplementation is very important, in addition to the prescription therapy below.
- B. Treatment choices include the following (in order of scientifically based evidence of fracture reduction)
 1. Bisphosphonates (Must be taken first thing in the morning on an empty stomach with a full glass of plain water. The patient should not be recumbent and must wait 30 minutes before eating, drinking or taking other medications).

NOTE:

Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported in patients taking bisphosphonates. Most reported cases of bisphosphonate-associated osteonecrosis have been in cancer patients treated with intravenous bisphosphonates, but some have occurred in patients with postmenopausal osteoporosis. Known risk factors for osteonecrosis include a diagnosis of cancer, concomitant therapies (e.g., chemotherapy, radiotherapy, corticosteroids), poor oral hygiene, and co-morbid disorders (e.g., pre-existing dental disease, anemia, coagulopathy, infection). Providers are encouraged to discuss the possibility of this complication with their patients who are taking biphosphate therapy.

- a. Alendronate (Fosamax) 10 mg daily, 70 mg weekly, or 70 mg with 2800IU of Vitamin D weekly (Fosamax Plus D). This agent has been shown to decrease vertebral and hip fracture incidence in a variety of clinical circumstances
 - b. Risedronate (Actonel) 5 mg daily, 35 mg weekly, or 35mg weekly with daily calcium (Actonel with Calcium) . This agent has been shown to decrease vertebral fractures in a variety of clinical circumstances. It has also been shown to decrease hip fracture rate in a subset of patients.
 - c. Ibandronate (Boniva) 150 mg once monthly. This agent has been shown to decrease vertebral fracture in postmenopausal women. Its effect on hip fracture and non-vertebral fracture has not been conclusively demonstrated. This medicine must be taken first thing in the morning on an empty stomach with a full glass of water. The patient should not be recumbent and must wait 60 minutes before eating, drinking or taking other medications.
 - d. Ibandronate sodium (Boniva) 3mg IV every 3 months. This agent has been shown to increase bone mineral density and reduce the incidence of vertebral fractures. This agent must only be administered intravenously by a health care professional.
2. Teriparatide (sc PTH - Forteo)
- a. 20 mcg SQ daily for up to 2 years
 - b. This agent is the first approved in class to stimulate bone formation. It has been shown to increase vertebral bone density and reduce the incidence of vertebral and non-vertebral fractures.
 - c. Specific nursing instruction for patient self-administration is needed.
 - d. Potential side effects include dizziness, leg cramps, and transient increases in serum calcium.
 - e. There is also a black box warning that there is an increased incidence of osteosarcoma in rats related to dose and treatment duration. This agent should not be prescribed for patients who are at increased baseline risk for osteosarcoma. This includes Puget's disease, unexplained alkaline phosphatase elevations, open epiphyses, or prior radiation therapy involving the skeleton.
 - f. Teriparatide is often used in patients that can not tolerate bisphosphonates or who have failed bisphosphonates (Failure defined as ongoing fractures or significant decrease in bone mineral density while on sufficient treatment).
 - g. Teriparatide should not be used concomitantly with bisphosphonates due to an attenuation of the effect of teriparatide. However, bisphosphonates should be given after a course of teriparatide to prevent subsequent recurrence of bone loss.
 - h. Some suggest that teriparatide could be considered as a first line agent in the patient who has severe osteoporosis (presents with fractures and very low bone density (T-score less than -3.0). This is still controversial.
3. Selective Estrogen Receptor Modulators
- a. Raloxifene (Evista) 60 mg daily. This agent has been shown to decrease vertebral fracture rates, but has not been shown to decrease hip fracture rates in a prospective study.

- b. Studies suggest a decreased risk of breast cancer in patients treated with Raloxifene, although this is not an approved indication for treatment
 - c. Raloxifene usage is associated with an increased risk of thromboembolic disease.
4. Miacalcin Nasal Spray (200 units, 1 spray daily) This agent has been shown to modestly decrease vertebral fracture rates, but has not been shown to decrease hip fracture rates in a prospective study. Given the availability of other more efficacious agents, its routine usage is of limited value.
 5. Hormone Replacement Therapy: The WHI (Women's Health Initiative), a large prospective study, has shown a reduction in hip fracture using combined estrogen plus progesterone, however there are concerns about its long-term use. WHI did show an increase risk of breast cancer, heart disease, stroke syndromes and thromboembolic disease with usage of estrogen plus progesterone. The USPSTF recommends against the routine usage of combined estrogens and estrogen alone in postmenopausal women (Grade D recommendation).
 6. Another bisphosphonate (Etidronate or Didronel) is not FDA approved, but has shown a decrease in vertebral fracture rates when given cyclically. Usual dosage is 400 mg daily for 2 weeks. This is repeated every 3 months.

Assess Response to Therapy

When to check:

A follow-up DXA scan should be performed, preferably on the same machine, after 2-3 years of treatment

Definition of Response:

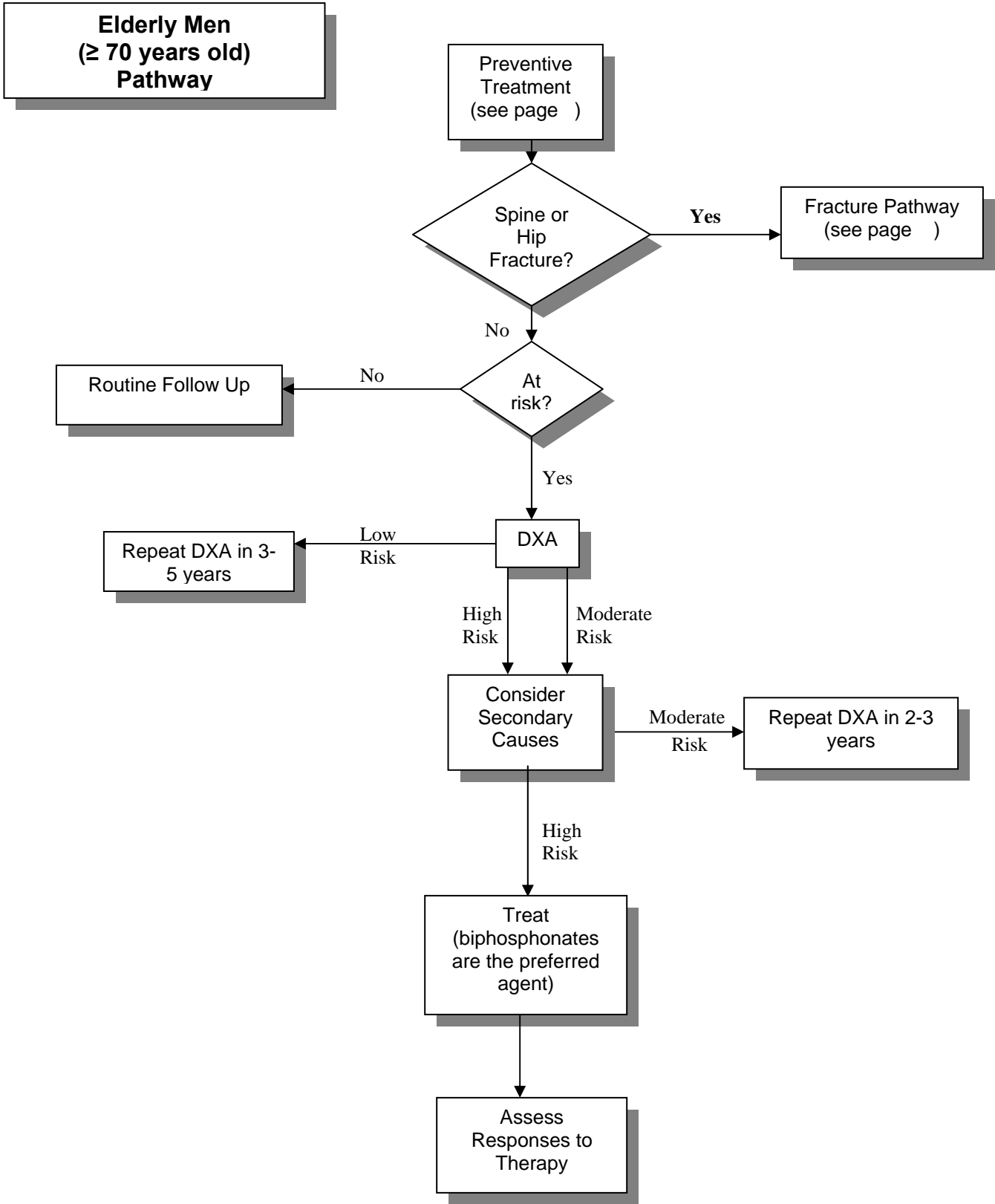
Good response - stabilization or significant improvement in bone density based on follow-up DXA, in the absence of an intercurrent fracture.

Poor response - significant loss of bone density on follow-up DXA OR an intercurrent fracture not related to major trauma despite adequate Calcium/Vitamin D and adherence to the prescribed treatment for at least 1 year.

What to do:

If the response is good, continue the regimen and repeat the DXA at the interval listed in the DXA report. If the response is poor, the patient should be queried about adherence to the prescribed regimen. In addition, a search for a secondary cause of osteoporosis should be initiated. Common tests to consider include: 25-OH Vitamin D, CBC, Comprehensive metabolic panel, Phosphorus, TSH, PTH, and ESR (or immunoelectrophoresis and quantitative immunoglobulins if there is a suspicion of myeloma). For EPIC providers, use Osteoporosis Smart Set [1146]. Finally, consider the addition of Teriparatide (sc PTH - Forteo)* and/or subspecialty referral as appropriate.

(*Note – Teriparatide (sc PTH - Forteo) requires specific patient administration education by a trained individual.)



Prevention

A. Lifestyle Changes

1. Weight Bearing and Balance Exercises performed for 20-30 minutes 3-5 times per week (Examples include walking, jogging, dancing, Tai Chi)
Smoking cessation (tobacco is considered a major risk factor)
2. Dietary changes to consume an adequate amount of calcium (1200-1500mg per day and vitamin D (400-800 IU per day) in divided doses if taken as a supplement
3. Make the patient's environment safer (good lighting, handrails, bathroom safety, avoid slippery surfaces and throw rugs)
4. Avoid high fracture risk behaviors (e.g. climbing ladders, stairs)
5. Consider hip protectors in the frail nursing home population.

B. Identify, Modify and Treat certain medical situations

1. Address musculoskeletal, neurological, and sensory problems which interfere with balance and increase the propensity to fall (e.g. include usage of canes, walkers, hearing aids, proper lighting)
2. Avoid sedating medications
3. Adjust thyroid medications to prevent over replacement

Spine or Hip Fracture

- A. Defined as a fracture of the spine or hip not related to major trauma.
- B. Vertebral fracture may be suspected because of pain or height loss, and confirmed by radiographs.

At Risk

DXA Scanning should be considered in the following settings:

- A. Demineralization on previous radiographs
- B. Spontaneous non-traumatic fractures
- C. Documented loss of height > 1.5 inches
- D. Chronic steroid use (> 7.5 mg/day for > 3 months or > 5 mg/day for > 6 months) – see steroid algorithm
- E. Primary hyperparathyroidism
- F. Men with prostate cancer who are on hormone therapy
- G. If patient or physician is concerned about osteoporosis and willing to take therapy (men > 70 have a significant increase in fracture rate, however, routine testing in men without one of the above risks may not be covered by insurers)

DXA Scan

- A. Best study for diagnosis and serial monitoring
- B. Vertebral fracture assessment (VFA) can be performed at the same time as DXA in at risk populations (per protocol).
- C. Interpreted in 3 risk categories

1. Low Risk (T score is above -1.0): A repeat study can be performed in 3-5 years
2. High Risk (T score is below -2.0 or below -1.5 with a major risk factor or nontraumatic hip or spine fracture): Prescription treatment is suggested in this situation. Repeat study in 2-3 years.
3. Moderate risk (T score is between the above two levels): No Prescription treatment is suggested but repeat DXA should be considered in 2-3 years.

Secondary Causes of Osteoporosis

A. Z-score and secondary causes of osteoporosis

1. The Z-score compares the person to an age/sex matched group
2. If the Z-score is low (below -1.0) or very low (below -2.0), then the person's BMD is much lower than others their age. This raises the concern about secondary causes of osteoporosis.

- B. If secondary causes are a concern, basic lab work may include 25-OH Vitamin D, CBC, Comprehensive metabolic panel, Phosphorus, TSH, PTH, total testosterone, and ESR (or immunoelectrophoresis and quantitative immunoglobulins if there is a suspicion of myeloma). For EPIC providers, use Osteoporosis Smart Set [1146]. Other tests or referrals may need to be considered as clinically appropriate or as suggested by disease.

Common Secondary Causes of Osteoporosis Include:

Endocrine/Metabolic
Hyperparathyroidism
Hypogonadism
Thyrotoxicosis

Nutritional

Alcoholism
Calcium deficiency
Malnutrition
Vitamin D deficiency

Drugs

Anticonvulsant therapy
Excessive thyroid medication
Glucocorticoids

Other

Hypercalciuria
Myeloma and some cancers
Rheumatoid arthritis

Uncommon Secondary Causes of Osteoporosis Include:

Endocrine/Metabolic

Acromegaly
Diabetes Mellitus, Type I

Hyperadrenocorticism
Hyperprolactinemia
Hypophosphatasia in adults
Porphyria
Systemic mastocytosis
Thalassemia

Nutritional

Anorexia Nervosa
Chronic liver disease
Gastric operations
Malabsorption syndromes

Drugs

Chronic heparin therapy

Collagen Metabolism

Ehlers-Danlos syndrome
Homocystinuria due to cystathione deficiency
Marfan syndrome
Osteogenesis imperfecta

Other

Down's syndrome
Immobilization (including spinal cord injuries)
Renal tubular acidosis

Modified from the AACE Medical guidelines for clinical practice for the prevention and management of postmenopausal osteoporosis: with selected updates for 2003. *Endocrine Practice* 2003; 9(6):544-564.

Treatment

- A. All patients follow the prevention guidelines noted above. Appropriate calcium and Vitamin D supplementation is very important, in addition to the prescription therapy below.
- B. Treatment choices include the following (in order of scientifically based evidence of fracture reduction)
- C. Bisphosphonates (Must be taken first thing in the morning on an empty stomach with a full glass of plain water. The patient should not be recumbent and must wait 30 minutes before eating, drinking or taking other medications).
 - 1. Alendronate (Fosamax) 10 mg daily, 70 mg weekly, or 70 mg with 2800 IU of Vitamin D weekly (Fosamax Plus D). This agent has been shown to increase bone density in men, and is currently the only drug approved for osteoporosis treatment in men.
 - 2. Risedronate (Actonel) 35mg weekly or 5 mg daily. This agent is not yet FDA approved for men but based on mechanism of action and efficacy in women would likely prove effective in increasing bone density in men.
 - 3. Teriparatide (sc PTH - Forteo)
 - a. 20 mcg SQ daily for up to 2 years

- b. This agent is the first approved in class to stimulate bone formation. It has been shown to increase vertebral bone density and reduce the incidence of vertebral and non-vertebral fractures.
 - c. Specific nursing instruction for patient self-administration is needed.
 - d. Potential side effects include dizziness, leg cramps, and transient increases in serum calcium.
 - e. There is also a black box warning that there is an increased incidence of osteosarcoma in rats related to dose and treatment duration. This agent should not be prescribed for patients who are at increased baseline risk for osteosarcoma. This includes Puget's disease, unexplained alkaline phosphatase elevations, open epiphyses, or prior radiation therapy involving the skeleton.
 - f. Teriparatide is often used in patients that can not tolerate bisphosphonates or who have failed bisphosphonates (Failure defined as ongoing fractures or significant decrease in bone mineral density while on sufficient treatment).
 - g. Teriparatide should not be used concomitantly with bisphosphonates due to an attenuation of the effect of teriparatide. However, bisphosphonates should be given after a course of teriparatide to prevent subsequent recurrence of bone loss.
 - h. Some suggest that teriparatide could be considered as a first line agent in the patient who has severe osteoporosis (presents with fractures and very low bone density (T-score less than -3.0). This is still controversial.
4. Very little data exists for other currently available drugs, which would include Miacalcin and etidronate.
 5. Treat secondary cause
 6. Assess Response to Therapy

When to check:

A follow-up DXA scan should be performed, preferably on the same machine, after 2-3 years of treatment

Definition of Response:

Good response - stabilization or significant improvement in bone density based on follow-up DXA, in the absence of an intercurrent fracture

Poor response - significant loss of bone density on follow-up DXA OR an intercurrent fracture not related to major trauma despite adequate Calcium/Vitamin D and adherence to the prescribed treatment for at least 1 year

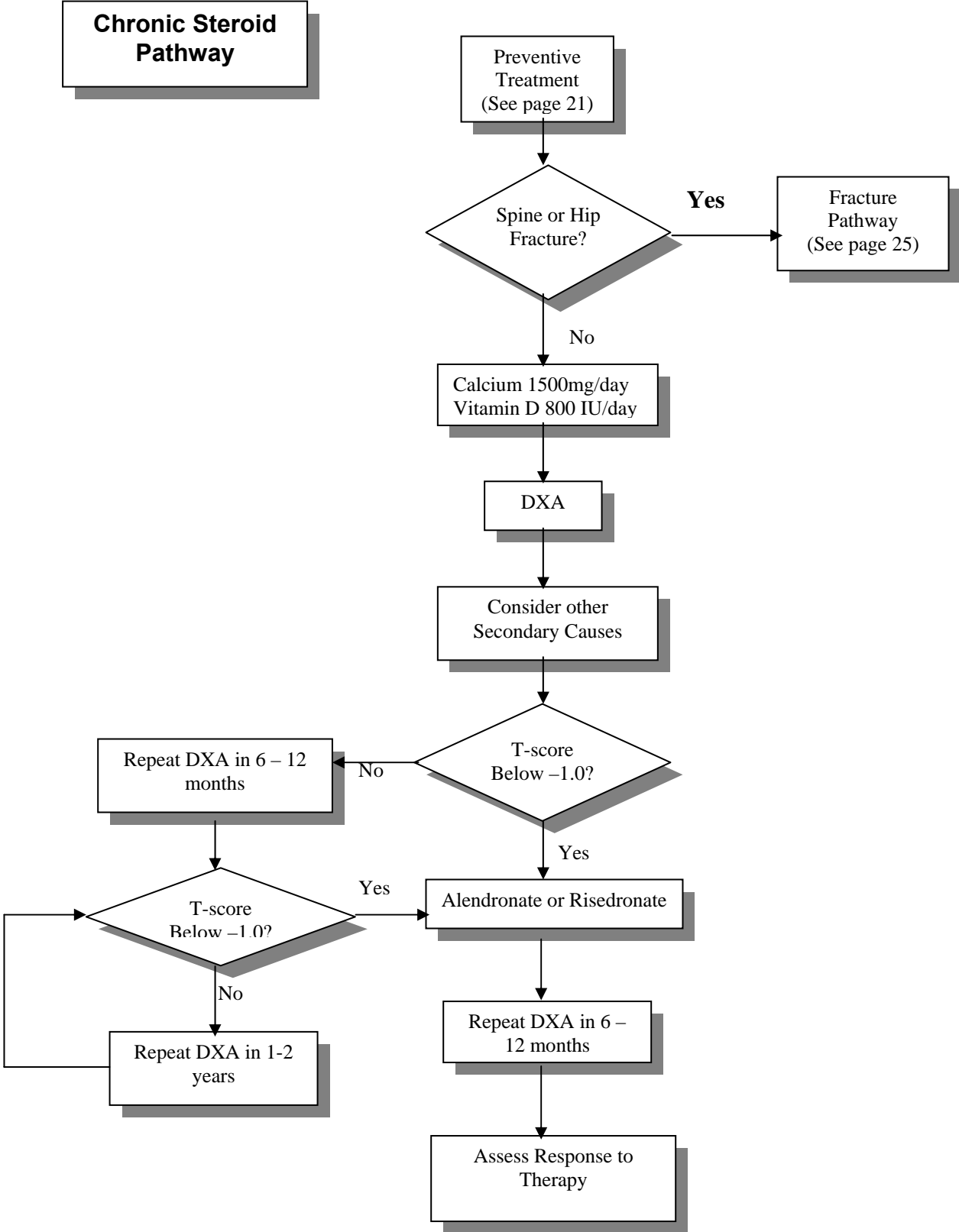
What to do:

If the response is good, continue the regimen and repeat the DXA at the interval listed in the DXA report

If the response is poor, the patient should be queried about adherence to the prescribed regimen. In addition, a search for a secondary cause of osteoporosis should be initiated. Common tests to consider include: 25-OH Vitamin D, CBC, Comprehensive metabolic panel, Phosphorus, TSH, PTH, total testosterone, and ESR (or immunoelectrophoresis and quantitative immunoglobulins if there is a suspicion of myeloma). For EPIC providers, use Osteoporosis Smart Set [1146].

Finally, consider the addition of Teriparatide (sc PTH - Forteo)* and/or subspecialty referral as appropriate.

*(*Note – Teriparatide (sc PTH - Forteo) requires specific patient administration education by a trained individual)*



Prevention**A. Lifestyle Changes**

1. Adequate intake of calcium and vitamin D – 1500mg of calcium and 800 IU of Vitamin D daily – much higher doses of Vitamin D may be necessary. A 25-OH Vitamin D level should be checked and levels maintained ≥ 30 ng/ml if possible.
2. Weight Bearing Exercises aimed at maintaining muscle mass
3. Smoking cessation (tobacco is considered a major risk factor)
4. Make the patient's environment safer (good lighting, handrails, bathroom safety, avoid slippery surfaces and throw rugs)
5. Avoid high risk behaviors (Example: climbing ladders)

B. Identify, Modify and Treat certain medical situations

1. Address Musculoskeletal, Neurological, and Sensory problems, which interfere with balance and increase the propensity to fall (Examples include usage of canes, walkers, hearing aids, etc.)
2. Avoid sedating medications
3. Adjust thyroid medications to prevent over replacement

C. Attempt to keep dose of steroids as low as possible or consider alternative forms as appropriate. (i.e. inhaled steroids, topical steroids)**Spine or Hip Fracture**

1. Defined as a fracture of the spine or hip not related to major trauma.
2. Vertebral fracture may be suspected because of pain or height loss, and confirmed by radiographs.

B. DXA

1. DXA is the test of choice for fracture risk assessment and monitoring in patients taking glucocorticoids.
2. DXA Interpretation
3. T-score: a low T-score means that the patient's fracture risk is increased. Patients on glucocorticoids tend to fracture at a higher bone density, so our threshold for recommending treatment is more liberal (T-score below -1.0)
4. Z-score: a low Z score means that the patient's bone density is low compared to healthy people of the same age and sex. If the Z-score is below -1.0 or certainly if below -2.0 , a work up for secondary causes of osteoporosis should be considered. However, a low Z-score in this setting may simply reflect the glucocorticoid use itself.

C. Repeating the DXA

1. Patients on glucocorticoids tend to lose bone most acutely during the first 6 months of treatment. Therefore, a repeat DXA is suggested in 6-12 months. If the patient's bone density has not fallen significantly, then the repeat DXA interval can be lengthened to 1-2 years
2. Response to treatment: because the loss of bone density with glucocorticoids can be profound, the acceptable goals of treatment may be different than in postmenopausal osteoporosis. Stability of bone density is not considered a reason for changing treatment – consider a change only if the patient continues to lose bone despite adherence to

treatment. If the patient sustains a fracture while on therapy, consideration should be given to specialty referral as appropriate.

Secondary Causes of Osteoporosis

- A. Basic lab work may include CBC, calcium, bun, creatinine, alk. phos., phosphorus, TSH, ESR, PTH, 25-OH Vitamin D, total testosterone level (men only) and ESR (or immunoelectrophoresis and quantitative immunoglobulins if there is a suspicion of myeloma). Other tests or referrals may need to be considered as clinically appropriate or as suggested by disease.
- B. There may be other clinical scenarios (such as non-traumatic fracture at an early age) that warrant consideration of secondary causes of osteoporosis.

Common Secondary Causes of Osteoporosis Include:

Endocrine/Metabolic

- Hyperparathyroidism
- Hypogonadism
- Thyrotoxicosis
- Diabetes Mellitus, Type I

Nutritional

- Alcoholism
- Malabsorption diseases
- Anorexia Nervosa
- Malnutrition
- Vitamin D deficiency
- Celiac disease

Drugs

- Anticonvulsant therapy**
- Excessive thyroid medication
- Glucocorticoids

Other

- Rheumatoid arthritis

Uncommon Secondary Causes of Osteoporosis Include:

- Endocrine/Metabolic
- Acromegaly
- Hyperadrenocorticism
- Hyperprolactinemia
- Hypophosphatasia in adults
- Porphyria
- Pregnancy
- Systemic mastocytosis
- Thalassemia

Nutritional

- Chronic liver disease
- Gastric operations
- Vitamin D deficiency
- Calcium deficiency

Drugs

- Chronic heparin therapy

Collagen Metabolism

- Ehlers-Danlos syndrome
- Homocystinuria due to cystathione deficiency
- Marfan syndrome
- Osteogenesis imperfecta

Other

- Down's syndrome
- Immobilization
- Renal tubular acidosis
- Myeloma and some cancers
- Hypercalciuria

Modified from the AACE Medical guidelines for clinical practice for the prevention and management of postmenopausal osteoporosis: with selected updates for 2003. *Endocrine Practice* 2003; 9(6):544-564.

Treatment (Alendronate/Risedronate, others)

1. All patients follow the prevention guidelines noted above. Appropriate calcium and Vitamin D supplementation is very important, in addition to the prescription therapy below.
2. Bisphosphonates are the only drugs that are FDA-approved for treatment of glucocorticoid-induced osteoporosis.
3. Bisphosphonates (Must be taken first thing in the morning on an empty stomach with a full glass of plain water. The patient should not be recumbent and must wait 30 minutes before eating, drinking or taking other medications).
 - a. Alendronate (Fosamax) 10 mg daily, 70 mg weekly, or 70 mg with 2800 IU of Vitamin D weekly (Fosamax Plus D).
 - b. Risedronate (Actonel) 5 mg daily or 35mg weekly.
4. If bisphosphonates cannot be used, consider specialty referral or use of Teriparatide (*sc PTH Forteo – off label use*)
 - a. 20 mcg SQ daily for up to 2 years
 - b. This agent is the first approved in class to stimulate bone formation. It has been shown to increase vertebral bone density and reduce the incidence of vertebral and non-vertebral fractures.
 - c. Specific nursing instruction for patient self-administration is needed.

- d. Potential side effects include dizziness, leg cramps, and transient increases in serum calcium.
 - e. There is also a black box warning that there is an increased incidence of osteosarcoma in rats related to dose and treatment duration. This agent should not be prescribed for patients who are at increased baseline risk for osteosarcoma. This includes Puget's disease, unexplained alkaline phosphatase elevations, open epiphyses, or prior radiation therapy involving the skeleton.
 - f. Teriparatide is often used in patients that can not tolerate bisphosphonates or who have failed bisphosphonates (Failure defined as ongoing fractures or significant decrease in bone mineral density while on sufficient treatment).
 - g. Teriparatide should not be used concomitantly with bisphosphonates due to an attenuation of the effect of teriparatide. However, bisphosphonates should be given after a course of teriparatide to prevent subsequent recurrence of bone loss.
 - h. Some suggest that teriparatide could be considered as a first line agent in the patient who has severe osteoporosis (presents with fractures and very low bone density (T-score less than -3.0). This is still controversial.
5. Other agents to consider if bisphosphonates cannot be used
- a. Testosterone (transdermal or IM) if man with sex hormone deficiency (off label use)
 - b. Raloxifene (off label use)

Assess Response to Therapy

When to check:

An initial follow-up DXA scan should be performed, preferably on the same machine, after 6-12 months of treatment. If no significant worsening is seen (see below), the next DXA study can be performed 1-2 years later.

Definition of Response:

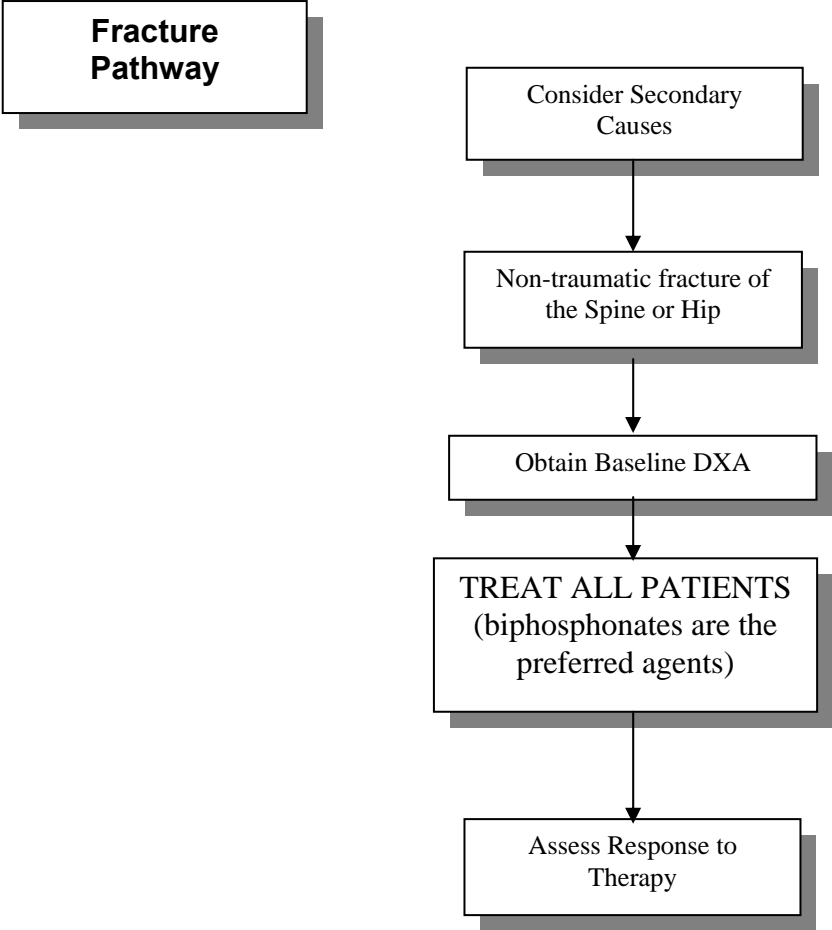
Good response – less than 5% loss in bone density based on follow-up DXA, in the absence of an intercurrent fracture

Poor response – greater than 5% loss in bone density on follow-up DXA OR an intercurrent fracture not related to major trauma despite adequate Calcium/Vitamin D and adherence to the prescribed treatment for at least 1 year

What to do:

If the response is good, continue the regimen and repeat the DXA at the interval listed in the DXA report

If the response is poor, the patient should be queried about adherence to the prescribed regimen. In addition, a search for a secondary cause of osteoporosis should be initiated. Common tests to consider include: 25-OH Vitamin D, CBC, Comprehensive metabolic panel, Phosphorus, TSH, PTH, total testosterone (men only), and ESR (or immunoelectrophoresis and quantitative immunoglobulins if there is a suspicion of myeloma). For EPIC providers, use Osteoporosis Smart Set [1146]. Finally, consider the addition of Teriparatide (sc PTH - Forteo)* and/or subspecialty referral as appropriate



Non-traumatic Spine or Hip Fracture

- A. All patients who sustain a non-traumatic spine or hip fracture should receive treatment – they are at high risk of future fracture.
 - 1. Defined as a fracture of the spine or hip not related to major trauma.
 - 2. Vertebral fracture may be suspected because of pain or height loss, and confirmed by radiographs.
 - 3. Preventive and Safety issues should be readdressed

Lifestyle Changes

- A. Weight Bearing and Balance Exercises performed for 20-30 minutes 3-5 times per week
(Examples include walking, jogging, dancing, Tai Chi)
- B. Smoking cessation (tobacco is considered a major risk factor)
- C. Dietary changes to consume an adequate amount of calcium (1200-1500mg per day and vitamin D (800 IU per day) in divided doses if taken as a supplement
- D. Make the patient’s environment safer (good lighting, handrails, bathroom safety, avoid slippery surfaces and throw rugs)
- E. Avoid high fracture risk behaviors (e.g. climbing ladders, stairs)
- F. Consider hip protectors in the frail nursing home population.

Identify, Modify and Treat Certain Medical Situations

- A. Address musculoskeletal, neurological, and sensory problems, which interfere with balance and increase the propensity to fall (e.g. include usage of canes, walkers, hearing aids, proper lighting)
- B. Avoid sedating medications
- C. Adjust thyroid medications to prevent over replacement

Secondary Causes of Osteoporosis

In all patients who sustain a non-traumatic fracture of the spine or hip, a search for a secondary cause of osteoporosis should be initiated. Common tests to consider include: 25-OH Vitamin D, CBC, Comprehensive metabolic panel, Phosphorus, TSH, PTH, total testosterone (men only), and ESR (or immunoelectrophoresis and quantitative immunoglobulins if there is a suspicion of myeloma). For EPIC providers, use Osteoporosis Smart Set [1146]. Other tests or referrals may need to be considered as clinically appropriate or as suggested by disease.

Common Secondary Causes of Osteoporosis Include:

Endocrine/Metabolic

- Hyperparathyroidism
- Hypogonadism
- Thyrotoxicosis

Nutritional

- Alcoholism
- Calcium deficiency
- Malnutrition

Vitamin D deficiency
Celiac disease

Drugs

Anticonvulsant therapy
Excessive thyroid medication
Glucocorticoids

Other

Hypercalciuria
Myeloma and some cancers
Rheumatoid arthritis

Uncommon Secondary Causes of Osteoporosis Include:

Endocrine/Metabolic

Acromegaly
Diabetes Mellitus, Type I
Hyperadrenocorticism
Hyperprolactinemia
Hypophosphatasia in adults
Porphyria
Systemic mastocytosis
Thalassemia

Nutritional

Anorexia Nervosa
Chronic liver disease
Gastric operations
Malabsorption syndromes

Drugs

Chronic heparin therapy

Collagen Metabolism

Ehlers-Danlos syndrome
Homocystinuria due to cystathione deficiency
Marfan syndrome
Osteogenesis imperfecta

Other

Down's syndrome
Immobilization
Renal tubular acidosis

Modified from the AACE Medical guidelines for clinical practice for the prevention and management of postmenopausal osteoporosis: with selected updates for 2003. Endocrine Practice 2003; 9(6):544-564.

DXA Scan

- A. Best study for diagnosis and serial monitoring
- B. Based on the presence of a non-traumatic spine or hip fracture, this patient would be considered at high risk of future fracture regardless of their bone density. The bone density measurement in this case is to be used as a baseline for monitoring purposes.
- C. If the patient has a low Z-score, it may prompt considering secondary causes of osteoporosis. The Z-score compares the person to an age/sex-matched group. If the Z-score is low (below -1.0) or very low (below -2.0), then the person's BMD is much lower than others their age. This raises the concern about secondary causes of osteoporosis.

Treatment

- A. All patients follow the prevention guidelines noted above. Appropriate calcium and Vitamin D supplementation is very important, in addition to the prescription therapy below.
- B. Treatment choices include the following (in order of scientifically based evidence of fracture reduction)

Women: Bisphosphonates (Fosamax, Actonel) are the preferred choice. Teriparatide (sc PTH - Forteo) may be considered initially if the BMD is very low and the patient has already had a hip or spine fracture. Other choices include raloxifene (Evista), calcitonin (Miacalcin).

Men: Fosamax is the preferred choice. Actonel would be an alternative (off label use). Teriparatide (sc PTH - Forteo) may be considered initially if the BMD is very low and the patient has already had a hip or spine fracture.

1. Bisphosphonates (Must be taken first thing in the morning on an empty stomach with a full glass of plain water. The patient should not be recumbent and must wait 30 minutes before eating, drinking or taking other medications).
 - a. Alendronate (Fosamax) 10 mg daily, 70 mg weekly, or 70 mg with 2800 IU of Vitamin D weekly (Fosamax Plus D). This agent has been shown to increase bone density and decrease fracture rate. It is currently the only drug approved for osteoporosis treatment in men.
 - b. Risedronate (Actonel) 35mg weekly or 5 mg daily. This agent has been shown to increase bone density and decrease fracture rate. It is not yet FDA approved for men but based on mechanism of action and efficacy in women would likely prove effective in increasing bone density in men.
 - c. Denosumab (Prolia) 120 mg every 6 months. This agent has been shown to increase bone density and decrease fracture rate. It is not yet FDA approved for men but based on mechanism of action and efficacy in women would likely prove effective in increasing bone density in men.
2. Teriparatide (sc PTH - Forteo)
 - a. 20 mcg SQ daily for up to 2 years
 - b. This agent is the first approved in class to stimulate bone formation. It has been shown to increase vertebral bone density and reduce the incidence of vertebral and non-vertebral fractures.
 - c. Specific nursing instruction for patient self-administration is needed.

- d. Potential side effects include dizziness, leg cramps, and transient increases in serum calcium.
- e. There is also a black box warning that there is an increased incidence of osteosarcoma in rats related to dose and treatment duration. This agent should not be prescribed for patients who are at increased baseline risk for osteosarcoma. This includes Puget's disease, unexplained alkaline phosphatase elevations, open epiphyses, or prior radiation therapy involving the skeleton.
- f. Teriparatide is often used in patients that can not tolerate bisphosphonates or who have failed bisphosphonates (Failure defined as ongoing fractures or significant decrease in bone mineral density while on sufficient treatment).
- g. Teriparatide should not be used concomitantly with bisphosphonates due to an attenuation of the effect of teriparatide. However, bisphosphonates should be given after a course of teriparatide to prevent subsequent recurrence of bone loss.
- h. Some suggest that teriparatide could be considered as a first line agent in the patient who has severe osteoporosis (presents with fractures and very low bone density (T-score less than -3.0). This is still controversial.

Assess Response to Therapy

For patients not on glucocorticoids:

When to check:

A follow-up DXA scan should be performed, preferably on the same machine, after 2 years of treatment.

Definition of Response:

Good response - stabilization or significant improvement in bone density based on follow-up DXA, in the absence of an intercurrent fracture

Poor response - significant loss of bone density on follow-up DXA OR an intercurrent fracture not related to major trauma despite adequate Calcium/Vitamin D and adherence to the prescribed treatment for at least 1 year

What to do:

If the response is good, continue the regimen and repeat the DXA at the interval listed in the DXA report

If the response is poor, the patient should be queried about adherence to the prescribed regimen. In addition, a search for a secondary cause of osteoporosis should be initiated. Common tests to consider include: 25-OH Vitamin D, CBC, Comprehensive metabolic panel, Phosphorus, TSH, PTH, total testosterone (men only), and ESR (or immunoelectrophoresis and quantitative immunoglobulins if there is a suspicion of myeloma). For EPIC providers, use Osteoporosis Smart Set [1146]. Finally, consider the addition of Teriparatide (sc PTH - Forteo)* and/or subspecialty referral as appropriate (*Note – Teriparatide [sc PTH – Forteo] requires specific patient administration education by a trained individual)

For patients on glucocorticoids:

When to check:

An initial follow-up DXA scan should be performed, preferably on the same machine, after 6-12 months of treatment. If no significant worsening is seen (see below), the next DXA study can be performed 1-2 years later.

Definition of Response:

Good response – less than 5% loss in bone density based on follow-up DXA, in the absence of an intercurrent fracture

Poor response – greater than 5% loss in bone density on follow-up DXA OR an intercurrent fracture not related to major trauma despite adequate Calcium/Vitamin D and adherence to the prescribed treatment for at least 1 year

What to do:

If the response is good, continue the regimen and repeat the DXA at the interval listed in the DXA report

If the response is poor, the patient should be queried about adherence to the prescribed regimen. In addition, a search for a secondary cause of osteoporosis should be initiated. Common tests to consider include: 25-OH Vitamin D, CBC, Comprehensive metabolic panel, Phosphorus, TSH, PTH, total testosterone (men only), and ESR (or immunoelectrophoresis and quantitative immunoglobulins if there is a suspicion of myeloma). For EPIC providers, use Osteoporosis Smart Set [1146]. Finally, consider the addition of Teriparatide (sc PTH - Forteo)* and/or subspecialty referral as appropriate (*Note – SC PTH (Forteo) requires specific patient administration education by a trained individual)

References

Geisinger Osteoporosis Program References

1. Newman ED, Lloyd T, Starkey R, Conroy P, Horwith M: Osteoporosis Clinical Practice Guideline. Penn State Geisinger Health System. 1998.
2. Newman ED, Welter R: Osteoporosis Disease Management: A Neglected Opportunity. Decision Resources 1999;3:1-12.
3. Newman ED, Ayoub W, Hanus P, Diehl J, Starkey R, Gutknecht D, Davis C, Neuner M: Osteoporosis Clinical Practice Guideline – 2nd Edition. Geisinger Health System 2000;1-24.
4. Newman ED, Starkey RH, Ayoub W, Davis C, Diehl J, Hanus P, Wood CG, Frey C: Osteoporosis Disease Management: Best Practices from the Penn State Geisinger Health System. J Clin Outcomes Man 2000;7(5):23-28.

5. Newman ED, Hanus P. Improved Bone Health Behavior Using Community Pharmacists As Educators: The Geisinger Health System Community Pharmacist Osteoporosis Education Program. *Disease Management and Health Outcomes* 2001;9(6):329-335.
6. Newman ED, Ayoub WT, Wood C: Glucocorticoid-induced osteoporosis – demographic analysis of at risk patients, diagnosis, and treatment in a rural primary care population. *Arthritis Rheum* 2001;44(9):S314.
7. Newman ED, Ayoub WT, Starkey RH, Wood C: The Geisinger Health System Osteoporosis Disease Management Program: significant improvement in diagnosis, treatment, and fracture rate and reduction in cost after 4 years. *Arthritis Rheum* 2001;44(9):S1604.
8. Newman ED, Ayoub WT, Starkey RH, Diehl JM, Wood GC: Osteoporosis Disease Management in a rural health care population: hip fracture reduction and reduced costs in postmenopausal women after 5 years. *Osteoporos International* 2003;14:146-151.
9. Newman ED, Oleginski TP, Hummel JT, Indeck CA, Wood GC. Improving osteoporosis diagnosis in rural-based patients using a mobile DXA program. *J Clin Densitom* 2003;6:182.
10. Newman ED, Ayoub WT, Matzko CK, Wood C. Glucocorticoid-induced osteoporosis – significant improvement in bisphosphonate use utilizing standardized consultative DXA reporting. *Arthritis Rheum* 2003;48:S499.
11. Newman ED: A schema for effective osteoporosis management – outcomes of the Geisinger Health System Osteoporosis Program. *Dis Manage Health Outcomes* 2003;11:611-616.
12. Newman ED, Oleginski TP, Perruquet JL, Hummel J, Indeck C, Wood GC. Using Mobile DXA to improve access to osteoporosis care. *J Clin Densitom* 2004;7:71-75.
13. Oleginski TP, Newman ED, Hummel JL, Hummer M. Implementation and evaluation of vertebral fracture using instant vertebral assessment. *Arthritis Rheum* 2004;50:S291.
14. Newman ED, Bryan-Smith L, Shapiro L. Referring physician relationship excellence: if you build it, they will come. *Arthritis Rheum* 2004;50:S661.
15. Newman ED, Matzko CK, Ayoub WT, Oleginski TP. Glucocorticoid-induced osteoporosis program (GIOP) – development and implementation of a novel care model to improve osteoporosis outcomes at a population level. *Arthritis Rheum* 2004;50:S664.
16. Newman ED, Matzko CK, Oleginski TP, Perruquet JL, Harrington TM, Wood GC, Culp T. GIOP: Comprehensive Care with Improved Outcomes. *Arthritis Rheum* 2005 52:S408.
17. Newman ED, Oleginski TP, Perruquet JL, Hummer J, Hummel M. At your service – implementation of a Mobile DXA Program to improve access to osteoporosis testing. *Arthritis Rheum* 2005 52:S408.
18. Oleginski TP, Newman ED, Hummel J, Hummer M. Development and Evaluation of a Vertebral Fracture Assessment Program using Instant Vertebral Assessment (IVA) and its Integration with Mobile DXA. *J Clin Densitom* 2005 (accepted for publication).

Other Guidelines and Position Statements

American Association of Clinical Endocrinologists:

AACE Medical guidelines for clinical practice for the prevention and management of postmenopausal osteoporosis: with selected updates for 2003. *Endocrine Practice* 2003; 9(6):544-564.

<http://www.aace.com/clin/guidelines/osteoporosis2001Revised.pdf>

National Osteoporosis Foundation:

Osteoporosis: review of the evidence for prevention, diagnosis and treatment and cost-effectiveness analysis (executive summary). *Osteoporosis Int.* 1998; 8(Suppl 4):S3-S6.

Surgeon General's Report:

Bone Health and Osteoporosis: A report of the Surgeon General.

<http://www.surgeongeneral.gov/library/bonehealth/>

Vitamin D:

1. Reginster J. The high prevalence of inadequate vitamin D levels and implications for bone health. *Current Med Research and Opinion* 2005;21:579-586
2. Hickey L, Gordon CM. Vitamin D deficiency: new perspectives on an old disease. *Curr Opin Endocrinol Diabetes* 2004;11:18-25.
3. Holick MF, Siris ES, et al. Prevalence of Vitamin D inadequacy among postmenopausal North American women receiving osteoporosis therapy. *J Clin Endocrinol Metab* 2005;90:3215-3224.

Glucocorticoid Induced Osteoporosis

1. Curtis JR, Westfall AO, et al. Longitudinal patterns in the prevention of osteoporosis in glucocorticoid-treated patients. *Arthritis Rheum* 2005;52:2485-2494.
2. Cohen D, Adachi JD. Review – treatment of glucocorticoid-induced osteoporosis. *J Steroid Biochem Molec Biology* 2004;88:337-349
3. Matzko CK, Newman ED, Perruquet JL, Olenigsk TP, Harrington TM, Wood GC, Culp T. GIOP: Comprehensive Care with Improved Outcomes. *Arthritis Rheum* 2005 52:S408.

Vertebral Fracture Assessment

1. Olenigski TP, Newman ED, Hummel J, Hummer M. Development and Evaluation of a Vertebral Fracture Assessment Program using Instant Vertebral Assessment (IVA) and its Integration with Mobile DXA. *J Clin Densitom* 2005 (accepted for publication).
2. Ross PD, Davis JW, Epstein RS, Wasnich RD. 1991 Pre-existing fractures and bone mass predict vertebral fracture incidence in women. *Ann Intern Med* 114:919-923.
3. Genant HK, Li J, Wu CY, Shepherd JA 2000 Vertebral fractures in osteoporosis: A new method for clinical assessment. *Journal of Clinical Densitometry* 3(3):281-290
4. Greenspan SL, van Stetten E, Emond EK, Jones L, Parker RA. 2001 Instant vertebral assessment: A noninvasive dual x-ray absorptiometry technique to avoid misclassification and clinical management of osteoporosis. *Journal of Clinical Densitometry* 4(4):373-380.
5. Rea JA, Blake GM, Sterger P, Genant HK, Fogelman I. 2000 Visual assessment of vertebral deformity by x-ray absorptiometry: A highly predictive method to exclude vertebral deformity. *Osteoporosis Int* 11:660-668.
6. Ross PD. 1996 Osteoporosis: frequency, consequences and risk factors. *Arch Med* 156:1399-1411.

7. Dubboeuf F, bauer DC, Chapurlat RD et al. Assessment of vertebral fracture using densitometric morphometry. *J Clin Densitom* 2005;8:362-368.

Alendronate

1. Black, DM, Cummings SR, Karpf DB, et al. (Fracture Intervention Trial Research Group). Randomized trial of effect of alendronate on risk of fracture in women with existing vertebral fractures. *Lancet*. 1996; 1535-1541.
2. Black, DM, Thompson DE, Bauer DC, et al. Fracture risk reduction with alendronate in women with osteoporosis: the Fracture Intervention Trial. *J Clin Endocrinol Metab*. 2000;85:4119-4124.
3. Cummings SR, Black DM, Thompson DE, et al. Effect of alendronate on risk of fracture in women with low bone density but without vertebral fractures: results from the Fracture Intervention Trial. *JAMA*. 1998;280:2077-2082.
4. Liberman UA, Weiss SR, Broll J, et al. (Alendronate Phase III Osteoporosis Treatment Study Group). Effect of oral alendronate on bone mineral density and the incidence of fractures in postmenopausal osteoporosis. *N Engl J Med*. 1995;333:1437-1443.
5. Orwell E, Ettinger M, et al. Alendronate for the treatment of osteoporosis in men. *N Engl J Med*. 2000;343:604-610.
6. Pols HA, Felsenberg D, Hanley DA, et al. Multinational, placebo-controlled, randomized trial of the effects of alendronate on bone density and fracture risk in postmenopausal women with low bone mass: results of the FOSIT study. *Osteoporosis Int*. 1999;9:461-468.
7. Saag KG, Emkey R, Schnitzer TJ, et al. (Glucocorticoid Induced Osteoporosis Study Group). Alendronate for the prevention and treatment of Glucocorticoid-induced osteoporosis. *N Engl J Med*. 1998;339:292-299.
8. Schnitzer T, Bone HG, Crepaldi G, et al. (Alendronate Once-Weekly Study Group). Therapeutic equivalence of alendronate 70 mg once weekly and alendronate 10 mg daily in the treatment of osteoporosis. *Aging (Milano)*. 2000;12:1-12.
9. Tonino RP, Meunier PJ, Emkey R, et al. Skeletal benefits of alendronate: 7-year treatment of postmenopausal osteoporotic women. *J Clin Endocrinol Metab*. 2000;85:3109-3115.

Risedronate

1. Cohen S, Levy RM, Keller M, et al. Risedronate therapy prevents corticosteroid-induced bone loss: a twelve-month, multi-center, randomized, double-blind, placebo-controlled, parallel-group study. *Arthritis Rheum*. 1999;42:2309-2318.
2. Fogelman I, Ribot C, et al. Risedronate reverses bone loss in postmenopausal women with low bone mass: results from a multinational, double-blind, placebo-controlled trial. *J Clin Endocrinol Metab*. 2000;85:1895-1900.
3. Harris ST, Watts NB, Genant HK, et al. (Vertebral Efficacy With Risedronate [VERT] Study Group). Effects of risedronate treatment on vertebral and nonvertebral fractures in women with postmenopausal osteoporosis: a randomized controlled trial. *JAMA*. 1999;282:1344-1352.
4. McClung MR, Geusens P, Miller PD, et al. (Hip Intervention Program Study Group). Effect of risedronate on the risk of hip fracture in elderly women. *N Engl J Med*. 2001;344:333-340.

5. Reginster JY, Minne HW, Sorensen OH, et al. (Vertebral Efficacy With Risedronate Therapy [VERT] Study Group). Randomized trial of the effects of risedronate on vertebral fractures in women with established postmenopausal osteoporosis. *Osteoporosis Int.* 2000;11:83-91.
6. Reid DM, Hughes RA, Laan RF, et al. Efficacy and safety of daily risedronate in the treatment of corticosteroid-induced osteoporosis in men and women: a randomized trial; European Corticosteroid-Induced Osteoporosis Treatment Study. *J Bone Miner Res.* 2000;15:1006-1013.

Teriparatide

1. Neer RM, Arnaud CD, Zanchetta JR, et al. Effect of parathyroid hormone (1-34) on fractures and bone mineral density in postmenopausal women with osteoporosis. *N Engl J Med* 2001;344:1434-1441.

Raloxifene

1. Delmas PD, Bjarnason NH, Mitlak BH, et al. Effects of raloxifene on bone mineral density, serum cholesterol concentrations, and uterine endometrium in postmenopausal women. *N Engl J Med.* 1997;337:1641-1647.
2. Ettinger B, Black DM, Mitlak BH, et al. (Multiple Outcomes of Raloxifene Evaluation [MORE] Investigators). Reduction of vertebral fracture risk in postmenopausal women with osteoporosis treated with raloxifene: results from a 3-year randomized clinical trial. *JAMA.* 1999;282:637-645.

Ibandronate

1. Chesnut CH, Ettinger MP, Miller PD, et al. Ibandronate produces significant, similar antifracture efficacy in North American and European women: new clinical findings from BONE. *Current Medical Research & Opinion* 2005;21:391-401.
2. Chesnut III CH, Skag A, Christiansen C, et al. Oral Ibandronate Osteoporosis Vertebral Fracture Trial in North America and Europe (BONE). Effects of oral ibandronate administered daily or intermittently on fracture risk in postmenopausal osteoporosis. *Journal of Bone & Mineral Research* 2004; 19:1241-9, 2004 A
3. Delmas PD, Recker RR, Chesnut CH 3rd et al. Daily and intermittent oral ibandronate normalize bone turnover and provide significant reduction in vertebral fracture risk: results from the BONE study. *Osteoporosis International* 2004;15):792-8.
4. McClung MR, Wasnich RD, Recker R, et al. Oral Ibandronate Study Group. Oral daily ibandronate prevents bone loss in early postmenopausal women without osteoporosis. *Journal of Bone & Mineral Research* 2004;19:11-8

Intranasal Calcitonin

1. Chestnut CH III, Silverman S, Andriano K, et al. (PROOF Study Group). A randomized trial of nasal spray salmon calcitonin in postmenopausal women with established osteoporosis: the Prevent Recurrence of Osteoporosis Fractures Study. *Am J Med.* 2000;109:267-276.

Estrogen

1. Rossouw JE, Anderson GL, Prentice RL, et al. Risks and benefits of estrogen plus

progestin in healthy postmenopausal women: principal results from the Women's Health Initiative randomized controlled trial. *JAMA* 2002; 288:321-33

2. Anderson, GL, Limacher M, Assaf AR, et al. Effects of conjugated equine estrogen in postmenopausal women with hysterectomy: the Women's Health Initiative randomized controlled trial. *JAMA* 2004;291:1701-12
3. U.S. Preventive Services Task Force. Hormone Therapy for the Prevention of Chronic Conditions in Postmenopausal Women: Recommendations from the U.S. Preventive Services Task Force. *Ann Intern Med.* 2005;142:855-60

Combination Pharmacologic Therapy

1. Lindsay R, Cosman F, Lobo RA, et al. Addition of alendronate to ongoing hormone replacement therapy in the treatment of osteoporosis: a randomized, controlled clinical trial. *J Clin Endocrinol Metab.* 1999;84:3076-3081.
2. Ravn P, Bidstrup M, Wasnich RD, et al. Alendronate and estrogen-progestin in the long-term prevention of bone loss: four-year results from the early postmenopausal intervention cohort study; a randomized, controlled trial. *Ann Int Med.* 1999;131:935-942.

Hip Protectors

1. Kannus, P, Parkkari, J, Niemi, S, et al. Prevention of hip fracture in elderly people with use of a hip protector. *N Engl J Med.* 2000;343:1506-1513.

Web Sites

National Osteoporosis Foundation - Physicians Guide to Prevention and Treatment of Osteoporosis. Review of the evidence for prevention, diagnosis, and treatment and cost-effectiveness analysis (executive summary). *Osteoporosis Int.* 1998; 8(Suppl 4):S3-36. Located at: www.nof.org/professionals

American Association of Clinical Endocrinologists: AACE 2001 Medical Guidelines for clinical practice for the prevention and management of postmenopausal osteoporosis. *Endocrine Practice* 2001; 7:293-312. 2001 Edition with selected updates for 2003. Located at: www.aace.com/clin/guidelines/osteoporosis2001revised.pdf.

American College of Rheumatology: Recommendation for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis – 2001 Update. Located at <http://www.rheumatology.org/publications/guidelines/index.asp?aud=mem>
Osteoporosis Prevention, Diagnosis, and Therapy. NIH Consensus Statement 2000 March 27-29; 17(1): 1-45. Located at: www.consensus.nih.gov/cons/111/111_intro.htm

AACE Osteoporosis Guidelines:<http://www.aace.com/pub/guidelines/>

MEASURES

- Percentage of mod/high risk members with bone mineral density (BMD)
- Percentage of high risk members on medication therapy
- Percentage of members with BMD and/or medication therapy post fracture