Osteoporosis

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The New Jersey Drug Utilization Review Board (NJDURB) assists the Division of Medical Assistance and Health Services and the Department of Health in the development of criteria and standards to be used in retrospective and prospective drug utilization review, to improve quality of care and reduce unnecessary expenditure. This guide contains information obtained from manufacturer's product package inserts, and is intended to provide healthcare professionals with a review of some of the uses and recommended dosing for the medications used to treat osteoporosis. This information is intended ultimately to help control the pharmacy program prescription costs without affecting the health and welfare of the patients who are prescribed these pharmacological classes of medications.

Osteoporosis is a skeletal disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures of the hip, spine, and wrist. There are two main categories of osteoporosis, Type I and Type II. Type I occurs only in post-menopausal women and is due to estrogen deficiency. Type II occurs in both men and women and is due to aging and calcium deficiency over many years.

	Type I	Type II
Age	50-70 yo	>70 yo
F:M ratio	6:1	2:1
Bone loss	Trabecular	Trabecular & cortical
Fractures	Vertebrae & distal radius	Vertebrae & hip
Main cause	Menopause-related	Age-related

Some Risk Factors for Osteoporosis

* FH_x: 1st degree relative with fracture
* ↑ Age
* Caucasian or Asian race
* Immobilization
* Calcium deficiency
* Long term steroids
* Phenytoin
* Heparin
* Excessive thyroxin
* Smoking
* Alcohol: > 7 drinks/wk
* Excessive caffeine
* Low body weight
* Early menopause
* Rheumatoid arthritis
* Hyperthyroidism
* ↓ Testosterone levels
* ↓ Physical activity

List of risk factors is not exhaustive

Clinical Presentation

* Silent disease: bone loss progresses w/o pain until a fracture occurs
* Fractures: vertebrae, hip, or forearm
* Kyphosis: curvature of the thoracic spine
* Protruding abdomen
* Chronic back pain
* Loss of height
* Ca^{2+}, $P0_{4-}$, Alkphos: within normal limits

Diagnosis

* World Health Organization's Bone Mineral Density (BMD) Classification:
* BMD: best predictor of fracture risk
  -for every 1 standard deviation ↓ in BMD fracture risk ↑ 1.5-3x
* T score: relates patient's BMD to the peak adult bone mass
* Tscore: Normal > -1
* Osteopenia: -1 to -2.5
* Osteoporosis: < -2.5

Osteoporosis | Osteopenia | Normal

-3	-2.6	-2.5	-1	0	+ 1	+2

Bone Mineral Density Testing Methods:
* Dual Energy X-ray Absorptiometry (DXA)
  -Prediction of fracture risk and monitoring response to therapies
*Others: Quantitative Computerized Tomography, Single Energy X-ray Absorptiometry, Quantitative Ultrasound

Who Should be Screened?

National Osteoporosis Foundation BMD Testing Recommendations:
* All postmenopausal women who have had a fracture
* Postmenopausal women who have one or more risk factors for osteoporotic fracture
* Women ≥ 65 y/o, regardless of their other risk factors for osteoporosis

Treatment Goals:

Prevent fractures:
* Stabilize or achieve a moderate increase in bone mass
* Relieve symptoms of fractures and skeletal deformity
* Maximize physical function

Non-Pharmacological Interventions:

* Engage in regular weight bearing exercises
* Avoid smoking and alcohol abuse
* RDA calcium: 1200-1500 mg Ca^{2+} qd
* RDA of vitamin D: 400-800 IU qd

Screening for Osteoporosis:

*Estrogen deficient women at risk for osteoporosis
*Individuals with vertebral abnormalities
*Individuals receiving long-term glucocorticoid therapy
*Individuals with primary hyperparathyroidism
*Individuals being monitored to asses the response to FDA-approved osteoporosis drug therapies
Above Reimbursed by Medicare Every Two Years

Medications for Osteoporosis: Prevention and Treatment[1]

Types	Therapeutic Class	Indication	Pregnancy Category	Dosage Forms	Dosage Administration	Side Effects
alendronate (Fosamax®)	Bisphosphonate	Prevents and treats osteoporosis in postmenopausal women & glucocorticoid-induced osteoporosis in women and men	C	~Oral: 5 mg QD or 35 mg weekly for prevention ~Oral: 10 mg QD or 70 mg weekly for treatment	~Medication should be taken on an empty stomach with a full glass of water in the morning while remaining in an upright position for at least 30 minutes ~Do not eat or drink for at least 30 minutes	~Abdominal or musculoskeletal pain, nausea, heartburn, irritation of the esophagus ~BBW[2]: osteonecrosis of the jaw
ibandronate (Boniva®)	Bisphosphonate	Prevents and treats osteoporosis in postmenopausal women	C	~Oral: 2.5 mg QD or 150 mg monthly for prevention and treatment ~IV: 3 mg dose every 3 months	~Take on an empty stomach with a full glass of water in the morning, remain in an upright position for at least an hour ~Do not eat or drink for at least an hour	~Abdominal or musculoskeletal pain, nausea, heartburn, irritation of the esophagus ~BBW[2]: osteonecrosis of the jaw
risedronate (Actonel®)	Bisphosphonate	Prevents and treats osteoporosis in postmenopausal women & glucocorticoid-induced osteoporosis in women and men	C	~Oral: 5 mg QD or 35 mg weekly for prevention and treatment	~Take on an empty stomach with a full glass of water first thing in the morning, remain in an upright position for at least 30 minutes ~Do not eat or drink for at least 30 minutes	~Abdominal or musculoskeletal pain, nausea, heartburn, irritation of the esophagus ~BBW[2]: osteonecrosis of the jaw
salmon calcitonin (Miacalcin®)	Calcitonin	Treats osteoporosis in postmenopausal women	B	~IM, SC: 100 IU SC every other day ~Intranasal: 200 IU/QD in alternating nostrils	Approved for use in women at least 5 years beyond menopause	~Intranasal: runny, irritated nose. ~Injection: flushing of the face and hands, frequent urination, nausea, and skin rash
teriparatide (Forteo®)	Parathyroid Hormone	Treats osteoporosis in postmenopausal women and men at high risk for fracture	C	~SC: 20 mcg injection QD in the thigh or abdomen	Approved for use up to 24 months	~Nausea, dizziness, and cramps ~BBW[2]: ↑ in osteo sarcoma
raloxifene (Evista®)	Selective Estrogen Receptor Modulator (SERM)	Prevents and treats osteoporosis in postmenopausal women	X	~Oral: 60 mg QD	May have a protective effect against breast cancer	~Hot flashes and venous thromboembolisms

Footnote:
1. Pamidronate (Aredia®) and zolendronate (Zometa ®) are two bisphosphonates that are used less in the community setting. They are indicated the treatment of hypercalcemia associated with malignancies.
2. Black Box Warning

Update: A recent randomized, double-blind clinical trial published in the December 27, 2006 issue of JAMA reported women at high risk for vertebral fractures would benefit from alendronate therapy if used beyond 5 years. After five years no statistically significant difference was found between women treated with alendronate versus placebo when measuring non-vertebral fracture risk. Long-term trials need to be conducted to determine the length of treatment for women being treated for osteoporosis with alendronate and other bisphosponates.

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