MedStar Health

Management of Osteoporosis

Clinical Practice Guideline

These guidelines are provided to assist physicians and other clinicians in making decisions regarding the care of their patients. They are not a substitute for individual judgment brought to each clinical situation by the patient's primary care provider-in collaboration with the patient. As with all clinical reference resources, they reflect the best understanding of the science of medicine at the time of publication, but should be used with the clear understanding that continued research may result in new knowledge and recommendations.

Introduction

Osteoporosis is a silent disease whose first clinical manifestation is usually a fracture, sometimes a major and disabling one. Based on data from the National Health and Nutrition Examination Survey III (NHANES III), the National Osteoporosis Foundation (NOF) has estimated that more than 9.9 million Americans have osteoporosis and an additional 43.1 million have low bone density of the hip. One out of every two white women will experience an osteoporotic fracture at some point in her lifetime. One in five men will have an osteoporosis related fracture in his lifetime. Osteoporosis is less common in African American women though represents the same risk of fracture once it occurs.[1]

Definition

Osteoporosis is a disease characterized by low bone mass, microarchitectural disruption, and increased skeletal fragility. The World Health Organization (WHO) defines osteoporosis as a bone mineral density measured by DEXA that is 2.5 or more standard deviations below the young adult reference mean.

Risk Factors for Osteoporosis and Osteoporotic Fractures

The factors associated with an increased risk of osteoporotic fracture can be characterized as modifiable or nonmodifiable. In general, the more risk factors a patient has, the greater the risk of fracture. If one or more risk factors are present, bone mineral density (BMD) testing may be indicated to determine whether therapy is appropriate.

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Non-Modifiable	Potentially Modifiable
▪ **Personal history of fracture as an adult**	▪ **Current cigarette smoking**
▪ **History of fracture in first-degree relative**	▪ Early menopause or bilateral oophorrectomy
▪ Female sex	▪ Prolonged premenopausal amenorrhea
	▪ (>1 year)
▪ Poor health/ frailty	▪ Alcohol (3 or more drinks/day)
▪ Caucasian race	▪ **Low body weight (<127 lbs)**
▪ Advanced age	▪ High intake Aluminum containing antacids
▪ Dementia	▪ Excess Vitamin A intake
	▪ Vitamin D insufficiency
	▪ High salt or caffeine intake
	▪ Low calcium intake (lifelong)
	▪ Impaired eyesight despite adequate correction
	▪ Poor health/frailty
	▪ Recurrent falls
	▪ Inadequate physical activity/immobilization

Note that poor health and frailty, which may or may not be modifiable, appear under both headings. **The four items in boldface—personal or family history of fracture, smoking, and low body weight—were demonstrated in a large, ongoing, prospective US Study to be key factors in determining the risk of hip fracture (independent of bone density).**

Falls and the risk of a fall are an important part of the evaluation since the majority of osteoporosis-related fractures result from falls. The most important of these seem to be a personal history of falling, along with muscle weakness and gait, balance and visual deficits.

Environmental issues of concern which can often be modified to reduce risk include: lack of assistive devices in bathrooms, loose throw rugs, low level lighting, obstacles in the walking path, and slippery outdoor conditions.

Medical conditions may also increase the risk of fall. They include: previous fall, age, anxiety, arrhythmias, dehydration/orthostatic hypotension, female gender, impaired transfer and mobility, reduced proprioception, muscle weakness, malnutrition, diminished mental acuity/cognitive functioning, urge incontinence, medications that cause sedation, kyphosis, and poor vision.

A recent study (Kannus & Parkkari, 2007, p. 454) suggested that in nursing home and institutions with high rates of hip fracture the use of hip protectors might help to reduce the risk of fracture. ―However there is no evidence of benefit from hip protectors for lower-risk (usually home dwelling) elderly people.

Diseases and Drugs Associated With an Increased Risk of Generalized Osteoporosis in Adults#

Diseases	Nutritional Conditions	Drugs	Disorders Of Collagen Metabolism	Other
Hypogonadism Hyperadrenocorticism Thyrotoxicosis Anorexia Nervosa Hyperprolactinemia Porphyria Hypophatasia In Adults Diabetes Mellitus Type 1 Pregnancy Hyperparathyroidism Acromegaly	Inf Bowel Disease, Malabsorption Syndromes and Malnutrition Chronic Liver Disease Gastric By pass Operations Vit. D Deficiency Alcoholism Primary Biliary Cirrhosis	Vitamin D Toxicity Phenytoin Glucocorticoids* Depo-medroxyprogesterone Phenobarbitol Excessive Thyroid Medication Heparin Gonadotropin-Releasing Hormone Agonists Lithium Cancer Chemotherapy Proton Pump Inhibitors Cyclosporine A and Tacrolimus Aromatase inhibitors	Osteogenesis Imperfecta Homocystinuria Due To Cystathionine Deficiency Ehlers-Danlos Syndrome Marfan Syndrome	Rheumatoid Arthritis Myeloma And Some Cancers Immobilization End stage renal disease Renal Tubular Acidosis Hypercalciuria COPD Organ Transplantation Sickle Cell Anemia Mastocytosis Thalassemia Muscular dystrophy and disuse states

Not an exhaustive list
*Glucocorticoids (≥ 5 mg/d of prednisone or equivalent for ≥ 3 mo)

Diagnosing Osteoporosis

A clinical diagnosis can often be made in at-risk individuals who sustain a low-trauma fracture, particularly at the hip or vertebrae. Bone mineral density testing should be performed to confirm the diagnosis and determine disease severity. Alternatively, the diagnosis of osteoporosis is established by measurement of BMD by DEXA with a T score lower than -2.5. Laboratory testing to exclude secondary causes of osteoporosis should be considered as appropriate.

Screening for Osteoporosis

1. Recommend BMD testing to all women aged 65 and older a regardless of additional risk factors.
2. In postmenopausal women and men over age 50, recommend BMD testing when you have concern based on their risk factor profile. The WHO FRAX tool can be used to estimate risk of osteoporosis.
3. Routine screening of men age 70 and older regardless of additional risk factors is not recommended by the USPSTF but is by the NOF and other groups.
4. There are no official guidelines regarding repeat screening in patients without osteoporosis on baseline measurement. Data from the Study of Osteoporotic Fractures, however, suggest that for women with normal or slightly low BMD at baseline, the interval between baseline testing and development of osteoporosis was approximately 17 yrs. For women with moderately low (T score -1.50—1.99) bone mass at baseline, transition to osteoporosis occurred at 4.7 yrs, and with low (T score -2.00—2.49) bone mass at baseline, transition to osteoporosis occurred at 1.1 yrs. This data suggests that re-screening intervals should be individualized.[9]

BMD TESTING

Bone mineral density (BMD) measurement can be used to establish or confirm a diagnosis of osteoporosis, predict future fracture risk, and monitor changes in BMD due to medical conditions or therapy. BMD has a continuous, graded, inverse relationship to the risk of fracture: **The lower the BMD, the greater the risk**. Some patients (ie, those over 70 with multiple risk factors) are at sufficiently high risk for osteoporosis that treatment is warranted without BMD testing. The decision to test for BMD should be based on an individual's risk profile, and testing is never indicated unless the results could influence a treatment decision.

BMD TESTING TECHNIQUES

1. Dual-energy x-ray absorptiometry (DXA or DEXA). DXA can be used to measure bone mineral density in the spine, hip, or wrist—the most common sites for osteoporotic fractures. DXA scans can be completed in a few minutes with radiation exposure that is approximately one tenth that of a standard chest x-ray. This is the most reliable measurement for both men and women.

2. Single-energy x-ray absorptiometry (SXA) and peripheral dual-energy x-ray absorptiometry (pDXA or pDEXA). These techniques measure bone density in the forearm, finger, and sometimes the heel. Measurement by validated pDXA devices can be used to assess vertebral and overall fracture risk in postmenopausal women. There is lack of sufficient evidence for fracture prediction in men. pDXA is associated with exposure to trivial amounts of radiation. pDXA is not appropriate for monitoring BMD after treatment.

3. Radiographic absorptiometry (RA). RA is a technique that is based on a standard x-ray or computer-generated x-ray of the hand with a metal wedge in the same field. RA is similar in accuracy and precision to SXA.

4. Quantitative computed tomography (QCT). QCT measures trabecular and cortical bone density at several sites in the body, but is most commonly used to measure trabecular bone density in the spine and hip. It may be used as an alternative to DXA for vertebral measurements and to predict spinal fractures in post menopausal women. Peripheral QCT, (pQCT) which measures BMD at forearm or tibia, can predict hip but not spine fractures. There is lack of sufficient evidence for fracture predication in men with this technology. Radiation exposure is higher than with DXA or pDXA.

5. Quantitative Ultrasound densitometry (QUS). **Quantitative ultrasound densitometry (QUS)** does not measure BMD directly but rather speed of sound (SOS) and/or broadband ultrasound attenuation (BUA) at the heel, tibia, patella and other peripheral skeletal sites. A composite parameter using SOS and BUA may be used clinically. Validated heel QUS devices predict fractures in postmenopausal women (vertebral, hip and overall fracture risk) and in men 65 and older (hip and non-vertebral fractures). QUS is not associated with any radiation exposure.It does not, however, have adequate sensitivity or specificity to confirm or exclude DXA diagnosed osteoporosis and cannot be used to monitor patients due to a lack of precision.

BONE MINERAL DENSITY MEASUREMENT AND CLASSIFICATION

Dual-energy x-ray absorptiometry (DXA) measurement of the hip and spine is the technology now used to establish or confirm a diagnosis of osteoporosis, predict future fracture risk and monitor patients by performing serial assessments. Bone Mineral Density is usually expressed in absolute terms of grams of mineral per square centimeter (g/cm^2) (technically known as areal BMD to distinguish it from volumetric BMD which is grams of mineral per cubic centimeter), and as a relationship to two norms: compared to the expected BMD for the patient's age and sex (Z-score), or compared to young normal adults of the same sex (T-score). The difference between the patient's score and the norm is expressed in standard deviations (SD) above or below the mean. Usually, 1 SD equals 10 to 15 percent of the BMD value in g/cm2. Depending upon the skeletal site, a decline in BMD expressed in absolute terms (g/cm^2) or in standard deviations (T-scores or Z-scores) begins during young adulthood, accelerates in women at menopause and continues to progress in postmenopausal women and men age 50 and older. The BMD diagnosis of normal, low bone mass, osteoporosis and severe or established osteoporosis is based on the WHO diagnostic classification. Although available technologies measuring central (spine and hip) and peripheral skeletal sites (forearm, heel, fingers) provide site-specific and global (overall risk at any skeletal site) assessment of future fracture risk, DXA measurement at the hip is the best predictor of future hip fracture risk.

In postmenopausal women and men age 50 years and older, the WHO diagnostic T-score criteria (normal, low bone mass and osteoporosis) are applied to BMD measurement by central DXA at the lumbar spine and femoral neck. BMD measured by DXA at the one-third (33 percent) radius site can be used for diagnosing osteoporosis when the hip and spine cannot be measured.

World Health Organization definitions based on BMD measurement at the spine, hip or forearm by DXA devices:

Bone Mass	Definition	T-Score
Normal	1 SD of a young normal adult	T-score above -1
Low bone mass (osteopenia)	Between 1 and 2.5 SD below that of a young normal adult	T-score between -1 and -2.5

Osteoporosis	2.5 SD or more below that of a young normal adult. Patients in this group who have already experienced one or more fractures are deemed to have severe or ―established osteoporosis.	T-score at or below -2.5

- *Although these definitions are necessary to establish the presence of osteoporosis, they should not be used as the sole determinant of treatment decisions.*

Indications for BMD Testing:

- Women age 65 and older and men age 70 and older, regardless of clinical risk factors
- Younger postmenopausal women and men age 50 to 69 about whom you have concern based on their clinical risk factor profile
- Women in the menopausal transition if there is a specific risk factor associated with increased fracture risk such as low body weight, prior low-trauma fracture or high risk medication
- Adults who have a fracture after age 50
- Adults with a condition (e.g., rheumatoid arthritis) or taking a medication (e.g., glucocorticoids in a daily dose ≥ 5 mg prednisone or equivalent for ≥ three months) associated with low bone mass or bone loss
- Anyone being considered for pharmacologic therapy for osteoporosis
- Anyone being treated for osteoporosis, to monitor treatment effect
- Anyone not receiving therapy in whom evidence of bone loss would lead to treatment

BMD measurement is not recommended in children or adolescents and is not routinely indicated in healthy young men or premenopausal women.

Medicare Part B covers BMD testing every 24 months (more often if medically necessary in the following situations:

- Estrogen deficient women at clinical risk for osteoporosis
- Individuals with xray evidence of osteoporosis, osteopenia or vertebral fracture
- Individuals receiving, or planning to receive, long-term glucocorticoid therapy in a daily dose ≥ 5 mg prednisone or equivalent for ≥ three months
- Individuals with primary hyperparathyroidism
- Individuals being monitored to assess the response or efficacy of an approved osteoporosis drug therapy

ADDITIONAL RISK ASSESSMENT WHO FRACTURE RISK ALGORITH (FRAX)

FRAX™ was developed to calculate the 10-year probability of a hip fracture and the 10-year probability of a major osteoporotic fracture (defined as clinical vertebral, hip, forearm or humerus fracture) taking into account femoral neck BMD and the clinical risk factors: age, gender, history of Rheumatoid arthritis, h/o prior fracture, parental history of hip fracture, current smoking, BMI, alcohol intake and prior use of glucocorticosteroids. The FRAX™ algorithm is available at https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9. Incorporation of the FRAX questionnaire is available on newer DXA scanners.

Treatment**:**

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

- A hip or vertebral (clinical or morphometric) fracture
- T-score ≤ -2.5 at the femoral neck or spine after appropriate evaluation to exclude secondary causes
- 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 algorithm (FRAX)

Calcium and vitamin D:

The Institute of Medicine recommends a total daily elemental calcium intake (in food plus supplementation) of 1000 mg for all adults 19-50 and men up to age 70, and 1200 mg for women > 50 years old and men > 70 years old. The IOM recommends a daily vitamin D intake of 600 IU daily for men and women up to age 70 and 800 IU for those > 70 years old.

Lifestyle modification:

Recommend regular weight-bearing and muscle-strengthening exercise to reduce the risk of falls and fractures.

Advise patients to avoid tobacco smoking and to keep alcohol intake moderate.

Medication:

Current FDA-approved pharmacologic options for osteoporosis prevention and/or treatment are bisphosphonates (alendronate, ibandronate, risedronate and zoledronic acid), calcitonin, estrogens and/or hormone therapy, parathyroid hormone (teriparatide), denosumab and estrogen agonist/antagonist (raloxifene). See Table for details.

Follow Up for patients on treatment**:**

Patient should be seen regularly to:

- Assess adherence to medicine
- Assess adequacy of calcium and vitamin D intake
- Reinforce lifestyle recommendations
- Monitor for side effects of therapy
- Monitor for signs and symptoms of vertebral fracture (back pain, loss of height, etc.)
- Consider repeat BMD measurement at 2 yr intervals if results would change management

Optimal duration of pharmacologic therapy is currently undefined and should be individualized based on fracture risk. Benefits of nonbisphosphonates wane upon discontinuation. Benefits of bisphosphonates on BMD and fracture risk may persist for several years after medication cessation. In addition, alendronate and zoledronic acid have been demonstrated to be safe and effective for 10 and 6 yrs respectively. Rare safety concerns related to bisphosphonates (osteonecrosis of the jaw and atypical femur fractures) become more frequent after 5 yrs of use. There is less data on the risks associated with Denosumab. The American Association of Oral and Maxillofacial Surgeons recommends performing extractions and implants as usual in patients who have been treated with oral bisphosphonates for less than four years and are not otherwise at risk for osteonecrosis of the jaw. They suggest discontinuing bisphosphonates for two months prior to performing the dental surgery if a patient has been treated for more than four years or has other risks for osteonecrosis. Bisphosphonates may be restarted when the bone has healed.

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Table: FDA-approved pharmacologic options for osteoporosis prevention and/or treatment

The anti-fracture benefits of FDA-approved drugs have mostly been studied in women with postmenopausal osteoporosis. There are limited fracture data in glucocorticoid-induced osteoporosis and no fracture data in men.

Drug	Indication	Dosing	Outcomes	Special Considerations	Cost*
Bisphosphonates					
Alendronate (Fosamax®)	Prevention (females only) Treatment Treatment secondary to glucocor-ticoids	5 mg/day or 35 mg/wk 10 mg/day or 70 mg/wk 5mg/day or 10mg/day in postmenopausal females not on estrogen	Reduces the incidence of fracture at the spine, hip, and wrist by about 50% over 3 yrs in patients with osteoporosis with or without prior spine fracture.	Must be taken on an empty stomach, first thing in the morning, with a large glass of water, sitting upright for at 30 minutes after administration and until after the first food of 30 minutes after administration and until after the first food of day. Causes esophageal Patients should remain upright during this interval. Cannot be taken at the same as calcium as it hinders absorption. Approved for treatment to increase bone mass in men and women with both osteoporosis and osteoporosis from glucocorticoids Renal function must be monitored	5mg: $88 10mg: $88 35mg: $82 70mg: $82
Alendronate + D (Fosamax® + D)	Treatment	70 mg/wk with 2800 IU vitamin D_3 or 70mg/wk with 5600 IU vitamin D_3			$208
Ibandronate oral (Boniva®)	Prevention and Treatment	150 mg/month	Reduces the incidence of spine fractures by about 50% over 3 yrs.	Should be taken on the same each month, at least 60 minutes before the first food, drink than water) or medication of day. Must be taken on an stomach, first thing in the with a glass of water. Patients must remain upright for at least 30 minutes after taking medication Monitor renal function	$139

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Drug	Indication	Dosing	Outcomes	Special Considerations	Cost
Ibandronate IV (Boniva®)	Treatment	3 mg every 3 months administered over a period of 15-30 seconds	No data	Intended for intravenous administration only. Should not be administered in patients with severe renal impairment (SCr >2.3 mg/dL) or CrCl < 30 mL/min. Jaw osteonecrosis has been reported with intravenous bisphosphonates. Most common side effects are flu-like symptoms.	$505
Risedronate (Actonel®)	Prevention and treatment (post-menopausal females) Treatment (males) Treatment secondary to gluco-corticoids	Immediate release: 5 mg/day or 35 mg/wk or 150mg/month Delayed release: 35mg once weekly (treatment only) 35 mg/wk (IR) 5mg/day	Risedronate reduces the incidence of spine fractures by 41-49% and non-spine fractures by 36% over 3 yrs in patients with a prior spine fracture.	Avoid with renal insufficiency. Cannot be taken at the same time as calcium as it hinders absorption. Immediate release tabs must be taken on an empty stomach, first thing in the morning, with a large glass of water, sitting upright for at least 30 minutes after administration and until after the first food of the day. Delayed release tabs must be taken with at least 4oz of water immediately after breakfast, sitting uprightfor at least 30 minutes after administration. Do not cut, split, crush, or chew. Approved for treatment to increase bone mass in men and women with both osteoporosis and osteoporosis from glucocorticoids. Actonel with Calcium is a co-package product containing Actonel (risedronate sodium tablets, 35 mg) which are taken once weekly and calcium	5mg: $266 35mg IR: $248 35mg EC: $209 150mg: $233

Drug	Indication	Dosing	Outcomes	Special Considerations	Cost
Zoledronic acid (Reclast®)	Treatment (including secondary to gluco-corticoids) Prevention	5 mg by IV infusion over at least 15 min once a year 5mg by IV infusion over at least 15 minutes once every 2 years	Reduces the incidence of vertebral fractures by about 70%, hip fractures by about 41% and non- vertebral fractures by 25% over 3 years.	Patients may be pretreated with acetaminophen to reduce the risk of an acute phase reaction (arthralgia, headache, myalgia, fever) with occurrence rates of 32% after first dose and 7% after 2nd dose and 3% after third dose Monitor renal function	$420
Per NOF Guidelines it is reasonable to discontinue biphosphonates after 3 to 5 years in people who appear to be at modest risk of fracture after the initial treatment period. For those who appear to be at high risk for fracture, continue treatment with a biphosphonate or an alternative therapy should be considered.					
Calcitonin					
Calcitonin (Miacalcin®)	Treatment	Single daily intranasal Spray providing 200 IU of the drug Also available in SQ and oral dosage form (100 units/day)	May reduce risk of vertebral fracture by 33%.	Indicated for women who are at least 5 years postmenopausal. Calcitonin is generally considered to be a safe but somewhat less effective intervention for osteoporosis. Causes esophageal irritation. Can cause rhinitis and epistaxis.	$119
Estrogen/Hormone Therapy					
HRT	Prevention		Women's Health Initiative found 5 yrs of therapy with one of the HRT (Pempro) reduced risk of vertebral and hip fractures by 24% and other fracture by 23%.	Since HRT may be associated with a modest increase in risk of breast cancer with long-term use and deep vein thrombosis, women with a history of, or at significant risk for, these conditions may be exceptions.	$$

Parathyroid Hormone					
Teriparatide (Forteo®)	Treatment	20 mcg daily SQ	Reduces risk of spine fractures by 65% and other fractures by 53% After 18 months of therapy.	To be used in postmenopausal women with high risk of fracture. Also to increase bone mass in men with primary or hypogonadal osteoporosis at high risk of fracture. Available as a 2.4 mL pen holds 30 doses. One pen can used for 30 days and then must discarded. Initial administration may cause orthostatis – patient should be able to sit or lie down if needed Osteosarcoma in animals has been reported and therefore should not be administered to people having a baseline risk of developing this condition. prior XRT, etc Max use 2 years. Safety and efficacy have not been demonstrated beyond 2 yrs of treatment.	$3597
Selective Estrogen Receptor Modulator					
Raloxifene (Evista®)	Prevention and Treatment	60 mg/day	Reduces the risk of spine fracture by 30% in patients with and by 55% in patients without a prior spine fracture, over 3 yrs.	Raloxifene increases the risk of deep vein thrombosis similar similar to estrogen. In addition, an increase in hot flashes is observed (~6% over placebo). May cause an increased chance of uterine cancer.	$64

Receptor Activator of Nuclear Factor kappa-B Ligand					
Denosumab (Prolia)	Treatment	60 mg SQ every 6 mos	Reduces the risk of fractures by 35% in a subset of women with more severe disease.	Denosumab may cause hypocalemia. Hypocalcemia must be corrected before Starting denosumab. It may increase the risk of serious skin infections and skin rash. If and when denosumab is stopped, bone loss can be rapid and alternative agents should be considered to maintain BMD.	$1354/inj (brand only)

AWP for 30 days of generic oral medicine and one syringe or infusion of parenteral medicine unless otherwise specified

HRT or estrogen replacement therapy should be considered for menopausal symptoms but should not be used to treat only osteoporosis unless all other modalities have been exhausted.

Patient Education**:**
Counsel all patients on the risk factors for osteoporosis.

Adequate Intake of Calcium and Vitamin D: Advise all patients to obtain an adequate intake of dietary elemental calcium (at least 1200 mg/d, including supplements if necessary) for women over 50 and men over 70 and 1000 mg/d for younger men and women and vitamin D_3 (600 IU per day for individuals under age 70, and 800 IU per day for adults age 70 and older). Vitamin D3 is the form of vitamin D that best supports bone health. Vitamin D can be obtained from fortified milk, egg yolks, saltwater fish, liver and supplements.

Regular Weight Bearing Exercise: Recommend regular weight-bearing and muscle- strengthening exercise to reduce the risk of falls and fractures. Includes walking, jogging, stair climbing, dancing, and tennis. Weight lifting improves muscle mass and bone strength.

Avoidance of Tobacco Use and Alcohol Abuse: Advise patients to avoid tobacco smoking and to keep alcohol intake moderate.

Resources for patients:
www.nof.org/resources/bonebasics
www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Osteoporsis
https://www.uptodate.com/contents/osteoporosis-the-basics?source=see_link
https://www.uptodate.com/contents/medicines-for-osteoporosis-the-basics?source=related_link

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Management of Osteoporosis Clinical Practice Guideline was initiated in 2007.

Clinical Guidelines are reviewed every two years by a committee of experts in the field. Updates to guidelines occur more frequently as needed when new scientific evidence or national standards are published.

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