



Guideline Summary NGC-8807

Guideline Title

American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis.

Bibliographic Source(s)

Watts NB, Bilezikian JP, Camacho PM, Greenspan SL, Harris ST, Hodgson SF, Kleerekoper M, Luckey MM, McClung MR, Pollack RP, Petak SM, AACE Osteoporosis Task Force. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. *Endocr Pract.* 2010 Nov-Dec;16 (Suppl 3):1-37. [209 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Hodgson SF, Watts NB, Bilezikian JP, Clarke BL, Gray TK, Harris DW, Johnston CC Jr, Kleerekoper M, Lindsay R, Luckey MM, McClung MR, Nankin HR, Petak SM, Recker RR, Anderson RJ, Bergman DA, Bloomgarden ZT, Dickey RA, Palumbo PJ, Peters AL, Rettinger HI, Rodbard HW, Rubenstein HA. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis: 2001 edition, with selected updates for 2003. *Endocr Pract* 2003 Nov-Dec;9(6):544-64.

Scope

Disease/Condition(s)

Postmenopausal osteoporosis

Guideline Category

Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Treatment

Clinical Specialty

Endocrinology
Family Practice
Geriatrics
Internal Medicine

Intended Users

Health Care Providers
Health Plans
Managed Care Organizations
Patients
Physicians
Public Health Departments

Guideline Objective(s)

- To reduce the risk of osteoporosis-related fractures and thereby improve the quality of life for people with

To reduce the risk of osteoporosis-related fractures and thereby improve the quality of life for people with osteoporosis

- To provide evidence-based information about the diagnosis, evaluation, and treatment of postmenopausal osteoporosis

Target Population

Postmenopausal women

Interventions and Practices Considered

Prevention/Risk Assessment

1. Assessment of postmenopausal osteoporosis risk factors using the Fracture Risk Assessment (FRAX) tool
2. Adequate calcium and vitamin D intake, through supplements as needed
3. Limiting alcohol and caffeine intake
4. Avoidance or cessation of smoking
5. Maintaining an active lifestyle

Diagnosis/Evaluation

1. Bone density measurement using dual-energy x-ray absorptiometry (DXA)
2. Evaluation for secondary osteoporosis and prevalent vertebral fractures

Treatment/Management

1. Adequate protein intake
2. Use of proper body mechanics
3. Use of hip protectors and protective measures to reduce risk of falling
4. Referral for physical and occupational therapy
5. Pharmacologic agents
 - First-line therapy: alendronate, risedronate, zoledronic acid, denosumab
 - Second-line therapy: ibandronate
 - Second- and third-line therapy: raloxifene
 - Last-line therapy: calcitonin
 - Bisphosphonate failure or very high fracture risk: teriparatide
6. Monitoring of treatment with change in bone density
7. Treatment holidays
8. Referral to a clinical endocrinologist

Note: Combination pharmacologic therapy was considered but not recommended; surgical repair of spinal fractures was considered but data were insufficient for a recommendation.

Major Outcomes Considered

- Mortality due to postmenopausal osteoporosis, particularly hip fracture
- Symptoms of fractures, skeletal deformity, and physical function
- Rates of bone loss
- Risk and incidence of fractures, falls, and injury
- Changes in bone mineral density measurements or bone turnover markers
- Side effects and cost effectiveness of treatment

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

PUBMED was searched and updates included papers published since the last guideline in 2003. Search terms used were: osteoporosis treatment and evaluation. Reviews and high level references were included. Opinion papers were not included.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

2010 American Association of Clinical Endocrinologists Criteria for Rating of Published Evidence*

Numerical Descriptor (evidence level)	Semantic Descriptor (reference methods)
1	Meta-analysis of randomized controlled trials
1	Randomized controlled trial
2	Meta-analysis of nonrandomized prospective or case-controlled trials
2	Nonrandomized controlled trial
2	Prospective cohort study
2	Retrospective case-control study
3	Cross-sectional study
3	Surveillance study (registries, surveys, epidemiologic study)
3	Consecutive case series
3	Single case reports
4	No evidence (theory, opinion, consensus, or review)

*1 = strong evidence; 2 = intermediate evidence; 3 = weak evidence; 4 = no evidence.

From Mechanick JI, Camacho PM, Cobin RH, et al (American Association of Clinical Endocrinologists Clinical Practice Guidelines Subcommittee). American Association of Clinical Endocrinologists protocol for standardized production of clinical practice guidelines—2010 update. *Endocr Pract*. 2010;16:270-283.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Expert opinion was used to evaluate the available literature and to grade references relative to evidence level (see the "Rating Scheme for the Strength of the Evidence" field), based on the ratings of 1 through 4 from the 2010 American Association of Clinical Endocrinologists (AACE) protocol for standardized production of clinical practice guidelines.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The guidelines used the best evidence, taking into consideration the economic impact of the disease and the need for efficient and effective evaluation and treatment of postmenopausal women with osteoporosis.

Recommendations were graded A through D, in accordance with methods established by the American Association of Clinical Endocrinologists (AACE) in 2004 (see the "Rating Scheme for the Strength of the Recommendations" field). Information pertaining to cost-effectiveness was included when available.

Rating Scheme for the Strength of the Recommendations

American Association of Clinical Endocrinologists Criteria for Grading of Recommendations

Recommendation Grade	Description
A	Homogeneous evidence from multiple well-designed randomized controlled trials with sufficient statistical power Homogeneous evidence from multiple well-designed cohort controlled trials with sufficient statistical power ≥1 conclusive level 1 publications demonstrating benefit >> risk
B	Evidence from at least 1 large well-designed clinical trial, cohort or case-controlled analytic study, or meta-analysis No conclusive level 1 publication; ≥1 conclusive level 2 publications demonstrating benefit >> risk
C	Evidence based on clinical experience, descriptive studies, or expert consensus opinion No conclusive level 1 or 2 publications; ≥1 conclusive level 3 publications demonstrating benefit >> risk No conclusive risk at all and no conclusive benefit demonstrated by evidence
D	Not rated No conclusive level 1, 2, or 3 publication demonstrating benefit >> risk Conclusive level 1, 2, or 3 publication demonstrating risk >> benefit

From Mechanick JI, Bergman DA, Braithwaite SS, Palumbo PJ (American Association of Clinical Endocrinologists Ad Hoc Task Force for Standardized Production of Clinical Practice Guidelines). American Association of Clinical Endocrinologists protocol for standardized production of clinical practice guidelines [published correction appears in *Endocr Pract.* 2008;14:802-803]. *Endocr Pract.* 2004;10:353-361.

Cost Analysis

- The cost-effectiveness of bone mineral density (BMD) testing and its benefits to society are controversial. Clinicians, politicians, patients, industry, and third-party payers all have different perspectives on the indications for and timing of BMD measurements. The current recommendations are intended to outline reasonable use of this technology within the context of the endocrine specialty practice. Because universal BMD testing is not cost-effective, the American Association of Clinical Endocrinologists (AACE) recommendations for screening include women 65 years of age or older and younger postmenopausal women at increased risk based on fracture risk analysis.
- AACE has endorsed the 2008 National Osteoporosis Foundation *Clinician's Guide to Prevention and Treatment of Osteoporosis*. The *Guide* recommends pharmacologic treatment for postmenopausal women with a T-score between -1.0 and -2.5 at high 10-year risk of fracture with use of the United States-adapted fracture risk assessment (FRAX) tool provided by the World Health Organization (WHO) at www.shef.ac.uk/FRAX, where treatment is considered cost-effective if the 10-year risk is 3% or more for hip fracture or 20% or more for "major" osteoporosis-related fracture (humerus, forearm, hip, or clinical vertebral fracture).

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

Not stated

Recommendations

Major Recommendations

The levels of evidence (**1** to **4**) and the recommendation grades (**A** to **D**) are defined at the end of the "Major Recommendations" field.

Executive Summary of Recommendations

The following recommendations (labeled "**R**") are evidence based (**Grades A, B, and C**) or are based on expert opinion because of a lack of conclusive clinical evidence (**Grade D**). The best evidence level (BEL), which corresponds to the best conclusive evidence found, accompanies the recommendation grade in this Executive Summary.

What Measures Can Be Taken to Prevent Bone Loss?

- R1.** Maintain adequate calcium intake; use calcium supplements, if needed, to meet minimal required intake (**Grade A; BEL 1**).
- R2.** Maintain adequate vitamin D intake; supplement vitamin D, if needed, to maintain serum levels of 25-hydroxyvitamin D [25(OH)D] between 30 and 60 ng/mL (**Grade A; BEL 1**).
- R3.** Limit alcohol intake to no more than 2 servings per day (**Grade B; BEL 2**).
- R4.** Limit caffeine intake (**Grade C; BEL 3**).
- R5.** Avoid or stop smoking (**Grade B; BEL 2**).
- R6.** Maintain an active lifestyle, including weight-bearing exercises for at least 30 minutes daily (**Grade B; BEL 2**).

What Nonpharmacologic Measures Can Be Recommended for Treatment of Osteoporosis?

All the foregoing measures plus the following:

- R7.** Maintain adequate protein intake (**Grade B; BEL 3**).
- R8.** Use proper body mechanics (**Grade B; BEL 1**).
- R9.** Consider the use of hip protectors in individuals with a high risk of falling (**Grade B; BEL 1**).
- R10.** Take measures to reduce the risk of falling (**Grade B; BEL 2**).
- R11.** Consider referral for physical therapy and occupational therapy (**Grade B; BEL 1**).

Who Needs to Be Screened for Osteoporosis?

- R12.** Women 65 years old or older (**Grade B; BEL 2**).
- R13.** Younger postmenopausal women at increased risk of fracture, based on a list of risk factors (see section 4.5 in the original guideline document) (**Grade C; BEL 2**).

How Is Osteoporosis Diagnosed?

- R14.** Use a central dual-energy x-ray absorptiometry (DXA) measurement (**Grade B; BEL 3**).
- R15.** In the absence of fracture, osteoporosis is defined as a T-score of -2.5 or below in the spine (anteroposterior), femoral neck, or total hip (**Grade B; BEL 2**).
- R16.** Osteoporosis is defined as the presence of a fracture of the hip or spine (see section 4.4.2 in the original guideline document) (in the absence of other bone conditions) (**Grade B; BEL 3**).

How Is Osteoporosis Evaluated?

- R17.** Evaluate for secondary osteoporosis (**Grade B; BEL 2**).

R18. Evaluate for prevalent vertebral fractures (see section 4.7.1 in the original guideline document) (**Grade B; BEL 2**).

Who Needs Pharmacologic Therapy?

R19. Those patients with a history of a fracture of the hip or spine (**Grade A; BEL 1**)

R20. Patients without a history of fractures but with a T-score of -2.5 or lower (**Grade A; BEL 1**)

R21. Patients with a T-score between -1.0 and -2.5 if Fracture Risk Assessment Tool (FRAX) (see section 4.5 in the original guideline document) major osteoporotic fracture probability is $\geq 20\%$ or hip fracture probability is $\geq 3\%$ (**Grade A; BEL 2**)

What Drugs Can Be Used to Treat Osteoporosis?

Use drugs with proven antifracture efficacy:

R22. Use alendronate, risedronate, zoledronic acid, and denosumab as the first line of therapy (**Grade A; BEL 1**).

R23. Use ibandronate as a second-line agent (**Grade A; BEL 1**).

R24. Use raloxifene as a second- or third-line agent (**Grade A; BEL 1**).

R25. Use calcitonin as the last line of therapy (**Grade C; BEL 2**).

R26. Use teriparatide for patients with very high fracture risk or patients in whom bisphosphonate therapy has failed (**Grade A; BEL 1**).

R27. Advise against the use of combination therapy (**Grade B; BEL 2**).

How Is Treatment Monitored?

R28. Obtain a baseline DXA, and repeat DXA every 1 to 2 years until findings are stable. Continue with follow-up DXA every 2 years or at a less frequent interval (**Grade B; BEL 2**).

R29. Monitor changes in spine or total hip bone mineral density (BMD) (**Grade C; BEL 2**).

R30. Follow-up of patients should be in the same facility, with the same machine, and, if possible, with the same technologist (**Grade B; BEL 2**).

R31. Bone turnover markers may be used at baseline to identify patients with high bone turnover and can be used to follow the response to therapy (**Grade C; BEL 2**).

What Is Successful Treatment of Osteoporosis?

R32. BMD is stable or increasing, and no fractures are present (**Grade B; BEL 2**).

R33. For patients taking antiresorptive agents, bone turnover markers at or below the median value for premenopausal women are achieved (see section 4.9 in the original guideline document) (**Grade B; BEL 2**).

R34. One fracture is not necessarily evidence of failure. Consider alternative therapy or reassessment for secondary causes of bone loss for patients who have recurrent fractures while receiving therapy (**Grade B; BEL 2**).

How Long Should Patients Be Treated?

R35. For treatment with bisphosphonates, if osteoporosis is mild, consider a "drug holiday" after 4 to 5 years of stability. If fracture risk is high, consider a drug holiday of 1 to 2 years after 10 years of treatment (**Grade B; BEL 1**).

R36. Follow BMD and bone turnover markers during a drug holiday period, and reinstate therapy if bone density declines substantially, bone turnover markers increase, or a fracture occurs (**Grade C; BEL 3**).

When Should Patients Be Referred to Clinical Endocrinologists?

R37. When a patient with normal BMD sustains a fracture without major trauma (**Grade C; BEL 4**).

R38. When recurrent fractures or continued bone loss occurs in a patient receiving therapy without obvious treatable causes of bone loss (**Grade C; BEL 4**).

R39. When osteoporosis is unexpectedly severe or has unusual features (**Grade C; BEL 4**).

R40. When a patient has a condition that complicates management (for example, renal failure, hyperparathyroidism, or malabsorption) (**Grade C; BEL 4**).

Definitions:

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2	Nonrandomized controlled trial
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2	Retrospective case-control study
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Clinical Algorithm(s)

None provided

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate screening, evaluation, management (including pharmacologic and nonpharmacologic treatment), and monitoring of women with osteoporosis or at high risk of osteoporosis

Potential Harms

- Side effects of pharmacotherapy
- Patients with severe osteoporosis should avoid engaging in motions such as forward flexion exercises, using heavy weights, or even performing side-bending exercises because pushing, pulling, lifting, and bending exert compressive forces on the spine that may lead to fracture. An initial visit with a physical therapist may help clarify what exercises are safe and unsafe to do.

Contraindications

Contraindications

Bisphosphonates

Contraindications to bisphosphonate therapy include hypersensitivity or hypocalcemia. Bisphosphonates should be used with caution, if at all, in patients with reduced kidney function (glomerular filtration rate below 30 mL/min for risedronate and ibandronate or below 35 mL/min for alendronate and zoledronate).

Raloxifene

Raloxifene is contraindicated in women of childbearing potential, those who have had venous thromboembolic disease, or those who are known to be hypersensitive to any component of raloxifene tablets.

Teriparatide

Because teriparatide caused an increased incidence of osteosarcomas in rats, it is contraindicated in patients at increased risk of osteosarcoma (those with Paget disease of bone, open epiphyses, a history of irradiation involving the skeleton, or an unexplained elevation of alkaline phosphatase level of skeletal origin). Teriparatide should also not be administered to

an unexplained elevation of alkaline phosphatase level of skeletal origin). Teriparatide should also not be administered to patients with primary or any form of secondary untreated or unresolved hyperparathyroidism.

Calcitonin

The main contraindication to use of calcitonin is hypersensitivity. For patients with suspected sensitivity to the drug, skin testing is recommended before treatment.

Estrogen and Menopausal Hormone Therapy

The following are contraindications to estrogen or combination estrogen-progestin therapy:

- Known or suspected pregnancy
- Known or suspected cancer of the breast
- Known or suspected estrogen-dependent neoplasm
- Undiagnosed abnormal genital bleeding
- Active thrombophlebitis or thromboembolic disorders or a history of thromboembolic disease
- Hypersensitivity to the hormones

Qualifying Statements

Qualifying Statements

These guidelines are a working document that reflects the state of the field at the time of publication. Because rapid changes in this area are expected, periodic revisions are inevitable. The American Association of Clinical Endocrinologists (AACE) encourages medical professionals to use this information in conjunction with their best clinical judgment. The presented recommendations may not be appropriate in all situations. Any decision by practitioners to apply these guidelines must be made in light of local resources and individual patient circumstances.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness
Staying Healthy

IOM Domain

Effectiveness
Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Watts NB, Bilezikian JP, Camacho PM, Greenspan SL, Harris ST, Hodgson SF, Kleerekoper M, Luckey MM, McClung MR, Pollack RP, Petak SM, AACE Osteoporosis Task Force. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. *Endocr Pract.* 2010 Nov-Dec;16 (Suppl 3):1-37. [209 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1996 Mar-Apr (revised 2010 Nov-Dec)

Guideline Developer(s)

American Association of Clinical Endocrinologists - Medical Specialty Society

Source(s) of Funding

Financial support for this guideline was provided by Wyeth-Ayerst Pharmaceuticals, Merck & Co., Inc., Proctor & Gamble Pharmaceuticals, Inc., Novartis Pharmaceuticals Corp., and Eli Lilly and Company.

Guideline Committee

Osteoporosis Task Force

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Chair

Dr. Nelson B. Watts reports that he has received speaker honoraria from Amgen Inc., the International Society for Clinical Densitometry, Novartis AG, and Warner Chilcott; consultant honoraria from Amgen Inc., Arena Pharmaceuticals, Inc., Baxter, InteKrin Therapeutics Inc., Johnson & Johnson Services, Inc., Medpace, Merck & Co., Inc., NPS Pharmaceuticals, Orexigen Therapeutics, Inc., Pfizer Inc, sanofi-aventis U.S. LLC, Takeda, VIVUS, Inc., and Warner Chilcott; and research grant support through the University of Cincinnati Osteoporosis Center from Amgen Inc., Eli Lilly and Company, Merck & Co., Inc., Novartis AG, and NPS Pharmaceuticals.

Task Force Members

Dr. John P. Bilezikian reports that he has received speaker honoraria from Amgen Inc., Eli Lilly and Company, and Novartis AG and consultant honoraria from Amgen Inc., Eli Lilly and Company, Merck & Co., Inc., and Warner Chilcott.

Dr. Pauline M. Camacho reports that she has received research grant support for her role as principal investigator from Eli Lilly and Company and Procter & Gamble.

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Dr. Stephen F. Hodgson reports that he does not have any relevant financial relationships with any commercial interests.

Dr. Michael Kleerekoper reports that he has received speaker honoraria from Amgen Inc. and Eli Lilly and Company and speaker and consultant honoraria from F. Hoffmann-La Roche Ltd Diagnostics.

Dr. Marjorie M. Luckey reports that she has received speaker honoraria and consultant fees from Amgen Inc. and Novartis AG.

Dr. Michael R. McClung reports that he has received research grant support, consulting fees, and/or speakers' bureau honoraria from Amgen Inc., Eli Lilly and Company, Merck & Co., Inc., Novartis AG, and Warner Chilcott.

Dr. Rachel Pessah Pollack reports that she does not have any relevant financial relationships with any commercial interests.

Dr. Steven M. Petak reports that he has received speaker honoraria from Amgen Inc. and the International Society for Clinical Densitometry.

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Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the [American Association of Clinical Endocrinologists \(AACE\) Web site](#).

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 245 Riverside Avenue, Suite 200, Jacksonville, FL 32202.

Availability of Companion Documents

The following is available:

- American Association of Clinical Endocrinologists protocol for standardized production of clinical practice guidelines—2010 update. *Endocrine Pract* 2010; 16:270-283. Electronic copies: Available in Portable Document Format (PDF) from the [American Association of Clinical Endocrinologists \(AACE\) Web site](#).

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 245 Riverside Avenue, Suite 200, Jacksonville, FL 32202.

Patient Resources

None available

NGC Status

This summary was completed by ECRI on August 28, 2001, and updated on February 13, 2004. The updated information was verified by the guideline developer on March 29, 2004. This summary was updated by ECRI on May 20, 2005, following the U.S. Food and Drug Administration advisory on Aredia (pamidronate disodium) and Zometa (zoledronic acid). This summary was updated by ECRI on June 16, 2005, following the latest U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This NGC summary was updated by ECRI Institute on February 14, 2012. The updated information was verified by the guideline developer on March 6, 2012.

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