



Osteoporosis Diagnosis and Treatment

OBJECTIVE

The objective of this Clinical Practice Guideline (CPG) is to provide evidence-based practice recommendations for the diagnosis and treatment of Osteoporosis. In addition, the CPG outlines the organizations that WellCare aligns with regarding Osteoporosis and relevant Measureable Health Outcomes.

OVERVIEW

Osteoporosis is a disease characterized by low bone mass and loss of bone tissue that may lead to weak and fragile bones. If you have osteoporosis, you have an increased risk for fractured bones, particularly in the hip, spine, and wrist. Osteoporosis is often considered to be a condition that frail elderly women develop. However, the damage from osteoporosis begins much earlier in life. Because peak bone density is reached at approximately 25 years of age, it is important to build strong bones by that age, so that the bones will remain strong later in life. Adequate calcium intake is an essential part of building strong bones. Nearly 10 million Americans have osteoporosis while 18 million people have low bone mass that places them at an increased risk for developing osteoporosis.¹

The following are risk factors for osteoporosis and osteoporotic fracture:²

- Advanced age (> 65)
- Caucasian or Asian race
- Body Habitus (weight < 127 lbs, BMI ≤ 20)
- Prior fragility fracture
- Parental history of hip fracture
- Smoking (active or passive)
- Daily alcohol use (3 or more units)
- Sedentary lifestyle and lack of physical activity (immobilization)
- Increased likelihood of falling due to environmental risk factors (e.g., lack of bathroom assistive devices, loose throw rugs, low lighting, slippery conditions, obstacles in walking path)

Medical risk factors that should be evaluated include:³

- Anxiety and/or depression
- Arrhythmias
- Dehydration
- Vitamin D insufficiency [serum 25-hydroxyvitamin D (25(OH)D) < 30 ng/ml (75 nmol/L)]
- Malnutrition
- Poor vision
- Reduced problem solving or mental acuity and diminished cognitive skills
- Urgent urinary incontinence

Providers should discuss the Member's risk pertaining to various conditions and diseases to ensure proper prevention measures are taken.³ Conditions and diseases that may increase one's risk of osteoporosis include:

- Genetic conditions
- Endocrine system, gastrointestinal and hematologic disorders
- Rheumatologic and autoimmune diseases
- Neurological and musculoskeletal risk factors (e.g., kyphosis, reduced proprioception, poor balance, weak muscles (sarcopenia), impaired transfer and mobility, deconditioning)
- Secondary causes of osteoporosis such as Type1 (insulin dependent) diabetes, osteogenesis imperfecta in adults, untreated long-standing hyperthyroidism, hypogonadism or premature menopause (<40 years), chronic malnutrition or malabsorption and chronic liver disease
- Miscellaneous conditions and diseases such as HIV/AIDS, alcoholism, amyloidosis, chronic metabolic acidosis, chronic obstructive lung disease, congestive heart failure, depression, end stage renal disease, hypercalciuria, idiopathic scoliosis, orthostatic hypotension, post-transplant bone disease, sarcoidosis and weight loss.

Certain medications may also increase a Member's risk of developing osteoporosis and should be discussed:³

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| • Aluminum (in antacids) | • Anticoagulants (heparin) | • Anticonvulsants |
| • Aromatase inhibitors | • Barbiturates | • Cancer chemotherapeutic drugs |
| • Depo-medroxyprogesterone (premenopausal contraception) | • Glucocorticoids (≥ 5 mg/d prednisone or equivalent for ≥ 3 months) | • GnRH (Gonadotropin releasing hormone) agonists |
| • Proton pump inhibitors | • Methotrexate | • Thyroid hormones (in excess) |
| • Lithium Cyclosporine A and tacrolimus | • Selective serotonin reuptake inhibitors | • Parental nutrition |
| • Tamoxifen® (premenopausal use) | Thiazolidinediones (such as Actos® and Avandia®) | |

BMD measurement with DXA is the single best imaging predictor of fracture risk as well as the best monitor of patient response to treatment. Measurements of BMD with DXA can predict fracture risk and allow for the identification of people who are at increased risk of fracture. Reviews of prospective cohort studies and case control studies have documented a direct relationship between decreasing BMD and increasing bone fracture risk. Additionally, there is strong evidence that stabilization or increases in BMD with therapy for osteoporosis are associated with substantial reductions in fracture incidence. Therefore, densitometry offers an objective measurement of a patient's response to treatment over time. At this time there are not cost effectiveness data for monitoring response to treatment. Current practice is to describe an individual's bone mineral density as compared to a reference normal population. In this sense, a T-score is the number of standard deviations above or below the mean for a gender- and ethnicity-matched young adult healthy population.⁴ Normal, low bone density (osteopenia) and osteoporosis are defined by the lowest of lumbar spine (at least two evaluable vertebrae required), femoral neck, and total femur T-score, according to the World Health Organization (WHO). The one-third radius site may be used if either the lumbar spine or femur is non-evaluable. The classifications below were drafted for Caucasian postmenopausal women, it also applies to men age 65 and older:

- **Normal:** a T-score greater than or equal to -1
- **Low bone density (osteopenia):** a T-score between -1 and -2.5
- **Osteoporosis:** a T-score less than or equal to -2.5

NOTE: The term "severe osteoporosis" is reserved for patients with a fragility fracture(s) and a low bone density.

Recommendations are outlined below from the American College of Obstetricians and Gynecologists (ACOG), American Association of Clinical Endocrinologists (AACE), and the National Osteoporosis Foundation (NOF).

Hierarchy of Support

GUIDELINE HIERARCHY

CPGs are updated annually or as necessary due to updates made to guidelines or recommendations by the American College of Obstetricians and Gynecologists (ACOG), American Association of Clinical Endocrinologists (AACE), and the National Osteoporosis Foundation (NOF). When there are differing opinions noted by national organizations, WellCare will default to the member's benefit structure as deemed by state contracts and Medicaid / Medicare regulations. If there is no specific language pertaining to osteoporosis, WellCare will default (in order) to the following:

- National Committee for Quality Assurance (NCQA);
- USPSTF, National Quality Strategy (NQS), Agency for Healthcare Research and Quality (AHRQ);
- Specialty associations, colleges, societies, etc. (e.g., American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, American Cancer Society, etc.).

Links to websites within the CPGs are provided for the convenience of Providers. Listings do not imply endorsement by WellCare of the information contained on these websites. NOTE: All links are current and accessible at the time of MPC approval.

WellCare aligns with the AACE, ACOG, and the NOF on the topic of osteoporosis. Highlights from respective publications are noted below.

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG)

The American College of Obstetricians and Gynecologists (ACOG)² published recommendations for screening and management of osteoporosis in women.

- Adolescent and adult women - counseling
- Women 65 years of age or older - screening
- Postmenopausal women with or at risk of developing osteoporosis - screening, prevention, treatment

Treatment should be recommended for:²

- Women with a T-score of -2.5 or less
- Women who have had low-trauma fracture
- Women who have a T-score from -1 to -2.5 and a fracture risk assessment tool (FRAX) score greater than or equal to 3% for risk of hip fracture or a FRAX score greater than or equal to 20% for risk of a major osteoporotic fracture (defined as forearm, hip, shoulder, or clinical spine fracture) or both in the next 10 years.

Therapies approved by the United States Food and Drug Administration (FDA) should be used for medical treatment: raloxifene, bisphosphonates, parathyroid hormone (PTH), denosumab, calcitonin. Bone density screening for women should begin at age 65 years. Dual-energy X-ray absorptiometry screening can be used selectively for women younger than 65 years if they are postmenopausal and have other significant risk factors for osteoporosis or fracture.²

The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B):²

- In the absence of new risk factors, dual-energy X-ray absorptiometry (DXA) screening should not be performed more frequently than every 2 years.
- In the absence of new risk factors, DXA monitoring of therapy should not be repeated once bone mineral density (BMD) has been determined to be stable or improved.
- Women should be counseled about lifestyle factors that may affect BMD and fracture risk: smoking, poor nutrition and excessive weight loss, weight-bearing/muscle-strengthening exercise, and fall-prevention.
- Women should be advised of current Institute of Medicine (IOM) calcium and vitamin D recommendations.

The following conclusion is based primarily on consensus and expert opinion (Level C):²

- The effect of lifestyle on bone health should be considered for girls and women of all ages and they should be counseled accordingly.

AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS (AACE)

The American Association of Clinical Endocrinologists (AACE) outlines recommendations for: prevention and screening measures for osteoporosis; diagnosis and evaluation; non-pharmacological and pharmacological treatment measures; and treatment monitoring success. A highlight of their recommendations are noted below – the full guideline can be accessed at <https://www.aace.com/files/osteo-guidelines-2010.pdf>:³

Prevention and Screening

The AACE recommends osteoporosis screening for women 65 years old or older and for younger postmenopausal women at increased risk of fracture, based on a list of risk factors. In addition, the AACE recommends the following:³

- Maintain adequate calcium intake; use calcium supplements, if needed, to meet minimal required intake.
- 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
- Limit alcohol intake to no more than 2 servings per day
- Limit caffeine intake
- Avoid or stop smoking
- Maintain an active lifestyle, including weight bearing exercises for at least 30 minutes daily

The American Association of Clinical Endocrinologists (AACE) note the following potential uses of BMD measurement in postmenopausal women:³

- Screening for osteoporosis
- Establishing the severity of osteoporosis or bone loss in patients with suspected osteoporosis (e.g., those with fractures or radiographic evidence of osteopenia)
- Determining fracture risk, especially when combined with other risk factors for fractures
- Identifying candidates for pharmacologic intervention
- Assessing changes in bone mass over time in treated and untreated patients
- Enhancing acceptance of, and perhaps adherence with, treatment
- Assessing skeletal consequences of diseases, conditions, or medications known to cause bone loss

Diagnosis and Referrals

The AACE recommends the following components of the diagnosis and evaluation of osteoporosis:³

- Use a central dual-energy x-ray absorptiometry (DXA) measurement
- 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
- Evaluate for secondary osteoporosis
- Evaluate for prevalent vertebral fractures

Providers may also need to refer a Member for the following when:³

- A Member with normal BMD sustains a fracture without major trauma
- Recurrent fractures or continued bone loss occurs in a Member receiving therapy without obvious treatable causes of bone loss
- Osteoporosis is unexpectedly severe or has unusual features
- A Member has a condition that complicates management (for example, renal failure, hyperparathyroidism, or malabsorption)

The AACE notes the following measures for decreasing the risk of osteoporosis and fractures in high-risk women:³

- Identify and treat women with osteoporosis-related fractures, and consider pharmacologic therapy for women with low bone mass
- Identify and treat sensory defects, neurologic disease, and arthritis, which can contribute to frequency of falls
- Adjust dosage of drugs with sedative effects, which could slow reflexes or decrease coordination and impair patient's ability to break impact of a fall
- Recommend appropriate lifestyle changes, including smoking cessation, increased weight-bearing activities, and dietary improvements
- Minimize risk of falls and injuries with gait and balance training

Treatment

Non-pharmacological treatment for osteoporosis includes:³

- Maintain adequate protein intake
- Use proper body mechanics
- Consider the use of hip protectors in individuals with a high risk of falling
- Take measures to reduce the risk of falling
- Consider referral for physical therapy and occupational therapy

Pharmacologic treatment measures for Member's with osteoporosis may be indicated for Members:³

- With a history of a fracture of the hip or spine
- Without a history of fractures but with a T-score of -2.5 or lower.
- With a T-score between -1.0 and -2.5 if FRAX the major osteoporotic fracture probability is $\geq 20\%$ or hip fracture probability is $\geq 3\%$

Drugs used to treat osteoporosis as a first line of therapy include alendronate, risedronate, zoledronic acid, and denosumab. Ibandronate is recommended as a second-line agent; raloxifene as a second- or third-line agent; and calcitonin as the last line of therapy. Teriparatide is indicated for Members with very high fracture risk or patients in whom bisphosphonate therapy has failed. Combination therapy is not advised.³

Treatment Monitoring Success

The AACE recommends the following to ensure that Providers monitor Members for treatment success:³

- 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.
- Monitor changes in spine or total hip bone mineral density (BMD).
- Follow-up should be in the same facility, with the same machine, and, if possible, with the same technologist.
- 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.
- BMD is stable or increasing, and no fractures are present.
- For those taking anti-resorptive agents, bone turnover markers at or below the median value for pre-menopausal women are achieved.
- 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.
- 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.
- Follow BMD and bone turnover markers during a drug holiday period, and reinstate therapy if bone.

NATIONAL OSTEOPOROSIS FOUNDATION

The National Osteoporosis Foundation⁴ offers recommendations on the clinical approach to managing osteoporosis in men and women age 50 and older (including postmenopausal women). Providers should:

- Obtain a detailed patient history pertaining to clinical risk factors for osteoporosis-related fractures and falls
- Perform physical examination and obtain diagnostic studies to evaluate for signs of osteoporosis and its secondary causes
- Modify diet/supplements, lifestyle and other modifiable clinical risk factors for fracture
- Estimate patient's 10-year probability of hip and any major osteoporosis-related fracture using the U.S.-adapted FRAX and perform vertebral imaging when appropriate to complete risk assessment
- Decisions on whom to treat and how to treat should be based on clinical judgment using this Guide and all available clinical information

Consideration of FDA-approved medical therapies should be based on the following:

- Vertebral fracture (clinical or asymptomatic) or hip fracture
- Hip DXA (femoral neck or total hip) or lumbar spine T-score ≤ -2.5
- Low bone mass (osteopenia) and a U.S.-adapted WHO 10-year probability of a hip fracture $\geq 3\%$ or 10-year probability of any major osteoporosis-related fracture $\geq 20\%$
- Preferences may indicate treatment for people with 10-year fracture probabilities above or below these levels.

Non-medical therapeutic interventions for consideration include:

- Modify risk factors related to falling
- Consider referrals for physical and/or occupational therapy evaluation (e.g., walking aids, assistive devices)
- Weight-bearing, muscle-strengthening exercise and balance training

Providers should consider the following items when seeing a member:

- Members not requiring medical therapies at the time of initial evaluation should be clinically re-evaluated when medically appropriate.
- Members taking FDA-approved medications should have laboratory and bone density re-evaluation after two years or more frequently when medically appropriate.
- To ensure no new vertebral fractures have occurred in the interval, vertebral imaging should be repeated with documented height loss, new back pain, postural change or suspicious finding on chest x-ray, following the last (or first) vertebral imaging test or in members being considered for a temporary cessation of drug therapy.
- Regularly (and at least annually), assess compliance and persistence with the therapeutic regimen.

The NOF recommends bone density testing in the following:⁴

- Women age 65 and older and men age 70 and older, regardless of clinical risk factors
- Younger postmenopausal women and men age 50-70 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 greater than or equal to 5 mg/day for three months or longer) associated with low bone mass or bone loss
- Anyone being considered for pharmacologic therapy for osteoporosis
- Anyone not receiving therapy in whom evidence of bone loss would lead to treatment
- Postmenopausal women discontinuing estrogen should be considered for bone density testing

Evidence Based Practice

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

The Agency for Healthcare Research and Quality (AHRQ) has published the following report(s):

- **Treatment To Prevent Fractures in Men and Women With Low Bone Density or Osteoporosis: Update of a 2007 Report**⁶ ([click here](#))

The report updates the 2007 review regarding the efficacy and safety of treatments used for fracture prevention. This report focuses on those with low bone density or osteoporosis as well as factors impacting treatment adherence.

MEASUREMENT OF COMPLIANCE

WellCare is committed to adhering to the measures and standards published by the Centers for Medicare and Medicaid Services (CMS) and the National Committee for Quality Assurance (NCQA). Please reference WellCare's Clinical Policy Guiding Document titled *Quality Improvement*.

NOTE: To access Clinical Policy Guiding Documents visit www.wellcare.com – select the Provider tab, then “Tools” and “Clinical Guidelines”.

Care Management

The goals for Care Management is to support the member's ability to self-manage their disease, minimize risks factors, and remove barriers preventing the member from achieving those goals.

Integrated care management of Osteoporosis involves:

- Educating member related to reducing risk of osteoporosis and osteoporotic fracture
- Ensuring member's understanding of medication dosing and adherence to medications, refilling timely
- Supporting the member's tobacco cessation efforts as appropriate
- Regular screening for co-morbidities (e.g., hypertension, obesity, cardiovascular disease)
- Assess for risk of depression and share with appropriate provider(s) if risks identified

Integrated care management of Osteoporosis involves:

- Educate member to discuss falls or problems with balance or walking with provider
- Assist with making appointment with provider

- Assist/arrange transportation to provider
- Assess need for and in obtaining assistive devices per treatment plan
- Educate member on home safety
- Educate member on taking medications as directed

MEASURABLE HEALTH OUTCOMES

Targeted Health Outcomes (Extended Program Goals) result from successful member self-management (see Case Management Objectives).

1. The Member experiences no symptoms requiring acute medical care and intervention. The case manager compares the recent utilization frequency for osteoporotic fracture to the frequency prior to CM engagement. CM monitors for ED and inpatient authorization/utilization related to osteoporotic fracture. In absence of ED and inpatient utilization, authorizations and claims data, or to otherwise demonstrate less frequent need for acute medical intervention, CM may use Provider and/or Member narrative.
2. Member participates in weight-bearing, muscle-strengthening exercise and balance training. Compare physical activity level documented in provider records, assessments and care plans, and monitoring data pre and post engagement 6-12 months. In the absence of these data sources, CM may use Provider and/or Member narrative and/or HRA data may be used.
3. Adherence to medication regimen, when appropriate, as evidenced by pharmacy claims pre and post engagement at 6-12 months. In absence of documentation, Provider and/Member narrative/HRA data may be used.

CASE MANAGEMENT GOALS

Case Goals should target specific care gaps and/or adherence issues, and measure the member's progress towards self-management and adherence which will lead to the targeted health outcomes above. Examples:

1. Member experiences no falls for a 60 day period with fall prevention strategies.
2. Member states implementation of appropriate interventions to minimize risk of injury within 10 days.
3. Member reports discussion regarding fall risks, concerns and prevention with doctor on [enter date]
4. Member demonstrates adherence to medication regimen as evidenced by pharmacy claims and member self-report in 90 days.
5. Member/caregiver will state understanding of signs and symptoms to report to doctor within 30 days.
6. Within 30 days, Member demonstrates reporting worsening symptoms to doctor same day.
7. Member/caregiver will verbalize understanding of risk factors that may increase symptoms within 30 days.
8. Member/caregiver states understanding of management techniques of osteoporosis within 5 days.
9. Member/caregiver reports following agreed upon osteoporosis management techniques and recommended treatment plan ordered by PCP/Specialist within 10 days.
10. Member has not required acute medical attention for osteoporosis in 30 days
11. Specific for Members requiring hospitalization: The Member participates in provider follow-up visit within 7 days of hospital discharge.

CASE MANAGEMENT OBJECTIVES

Case Management Objectives should focus on improving the Member's self-management skills including:

1. Fall risk prevention
2. Medication adherence, address barriers to medication adherence
3. Weight-bearing, muscle-strengthening exercise and balance training or as otherwise prescribed by physician
4. Following a diet low in saturated fat and cholesterol but high in fiber
5. Taking medications including statins as prescribed
6. Assist with scheduling Provider appointments and transportation as needed
7. Tobacco cessation
8. Avoiding second-hand smoke
9. Early identification of symptoms to manage, report to physician and / or call for emergency services
10. Educate member to discuss risks with Provider and discuss obtaining 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. Assist with appointment and transportation as needed.

11. Care manager will educate member/caregiver on potential signs and symptoms such as:

- Back pain, caused by a fractured or collapsed vertebra
- Loss of height over time
- A stooped posture
- A bone fracture that occurs much more easily than expected

Care manager will send educational materials to member/caregiver on osteoarthritis.
Member/caregiver will report worsening symptoms to PCP/specialist timely

12. Care manager will educate member/caregiver on risk factors such as:

- Women are much more likely to develop osteoporosis than are men
- The older you get, the greater your risk of osteoporosis
- Greatest risk of osteoporosis if you're white or of Asian descent
- Having a parent or sibling with osteoporosis puts you at greater risk, especially if your mother or father experienced a hip fracture
- Men and women who have small body frames tend to have a risk because they may have less bone mass to draw from as they age
- Smoking (active or passive)
- Daily alcohol use (3 or more units)
- Sedentary lifestyle and lack of physical activity (immobilization)
- Increased likelihood of falling due to fall risks in the home (lack of bathroom assistive devices, loose throw rugs, low lighting, slippery conditions, obstacles in walking path)
- Conditions like anxiety, depression, dehydration, vitamin D insufficiency, malnutrition, poor vision, thought process issues, urgent urinary incontinence

Care manager will send educational materials to member/caregiver on osteoporosis
Member/caregiver will report worsening symptoms to PCP/specialist timely
Member/caregiver will follow recommended treatment plan ordered by PCP/Specialist.

13. Member/caregiver will state understanding of purpose of bone density testing within 30 days.

14. Care manager will educate member/caregiver on purpose of bone density testing such as:

- A bone mineral density (BMD) test can provide a snapshot of your bone health. The test can identify osteoporosis, determine your risk for fractures (broken bones), and measure your response to osteoporosis treatment.
- It is painless—a bit like having an x-ray.
- A BMD test measures your bone mineral density and compares it to that of an established norm or standard to give you a score. Score meaning:

Normal: a T-score greater than or equal to -1

Low bone density (osteopenia): a T-score between -1 and -2.5

Osteoporosis: a T-score less than or equal to -2.5

Care manager will send educational materials to member/caregiver on bone density
Member/caregiver will be comfortable discussing bone density testing with PCP/specialist

15. Care manager will educate member/caregiver on management techniques such as:

- Don't smoke (as smoking increases the rate of bone loss)
- Avoid excessive alcohol (more than two alcoholic drinks a day may decrease bone formation)
- Prevent falls (wear low heeled shoes, install grab bars in shower, check house for electrical cords, area rugs and slippery surfaces that might cause you to trip or fall)
- Take prescribed medications as directed
- Attend all appointments as scheduled
- Report new or worsening symptoms to PCP/Specialist
- Exercise - weight bearing and muscle strengthening
- Keep a BMI between 20 and 25

Care manager will send educational materials to member/caregiver on osteoporosis

Care manager will assist member/caregiver with addressing identified barrier(s) to managing osteoarthritis
Member/caregiver will report worsening symptoms to PCP/specialist timely
Member/caregiver will follow recommended treatment plan ordered by PCP/Specialist.

The care team should also conduct screening for and treatment of anxiety and/or depression, as appropriate.

MEDICAL BEHAVIORAL INTEGRATION

Some psychotropic medications may decrease bone mineral density and increase risk of osteoporosis. Antidepressants have all been associated with an increased risk of bone fracture, particularly among older adults, by as much as 70-90%. SSRIs have the highest risk of osteoporotic fractures. One reason for the increase in fractures is falls due to dizziness as a common side effect, but even after adjusting for falls, the rates of bone loss are higher among those taking antidepressants. Many studies also suggest that depression and bipolar disorders on their own increase osteoporosis risk and a greater loss of bone over time. Women are at higher risk of fractures and bone loss as they are more likely to develop both mood disorders and osteoporosis as compared to men.⁷

MEMBER EDUCATIONAL RESOURCES

WellCare contracts with Krames/StayWell for Member educational materials utilized by Case Managers. Items are available to review with Members to address knowledge gaps. Case Managers verbally educate Members on the topics below related to asthma. (Titles may also be sent to the member).

NOTE: Links are internal for WellCare Care Management staff. Please see below for public links.

- [Preventing Falls Making Changes in Your living Space](#)
- [Preventing Falls Moving Safely Out of a Chair and Bed](#)
- [Preventing Falls Moving Safely Using a Cane or Walker](#)
- Exercises to Prevent Falls
- Preventing Falls Make Your Health a Priority

Providers may wish to research the titles above related to asthma that Case Managers utilize with Members.

PHARMACOLOGY

Gonadal Hormone Treatment: The use of supplemental estrogen in the immediate post-menopause has been well accepted in preventing the rapid loss of bone that occurs in this interval. Ultra-low estrogen supplementation has been shown to be effective in severely hypoestrogenic women in improving bone mass. The bone loss associated with male hypogonadism is reversed by testosterone therapy at least partly via aromatization to estrogen. Testosterone therapy, although not FDA-approved for osteoporosis, seems a reasonable first therapeutic intervention in men symptomatic with hypogonadism who do not have contraindications to the use of testosterone therapy.⁴

Bisphosphonates: Alendronate has been shown to increase bone mineral density and reduce the incidence of vertebral, hip, and non-vertebral fractures in postmenopausal women having existing vertebral fractures, and those with low bone mineral density (approximately 2.1 SD below peak) compared to placebo (calcium and vitamin D). Excellent clinical trial data based on BMD and bio-markers supports the use of oral bisphosphonates for preventing fractures in patients diagnosed with postmenopausal low bone density (osteopenia) or osteoporosis. The best clinical trials have been done with alendronate, risedronate, and ibandronate.^{2, 4}

Selective Estrogen Receptor Modulator (SERM): The only SERM approved for the prevention and treatment of osteoporosis is raloxifene. The MORE trial was a large 3-year randomized placebo-controlled study in postmenopausal women with osteoporosis. Raloxifene showed an increase in BMD and reduced the risk of vertebral fractures. The risk of non-vertebral fractures did not differ between placebo and raloxifene. There was an increased risk of venous thromboembolism compared with placebo (RR 3.1, 95% CI 1.5-6.2). The CORE 4-year trial extension of 4,011 women continuing from MORE (7,705) showed no difference in overall mortality, cardiovascular events, cancer or nonvertebral fracture rates. In the STAR trial, raloxifene was found comparable to tamoxifen for the prevention of invasive breast cancer. Thus, raloxifene appears to be the drug of choice for women with osteoporosis if the main risk is of spinal fracture and there is an elevated risk of breast cancer.⁴

Calcitonin: Nasal salmon-calcitonin 200 international units daily has shown a 33% risk reduction in new vertebral fractures compared with placebo (RR 0.67, 95% CI 0.47-0.97, p = 0.03). This occurred without significant effects on BMD. BMD measurements were not blinded to investigators and 59% (744) participants withdrew from the study early. Also, a dose response was not observed with respect to risk reduction of vertebral fractures.⁴

Follow-Up after Pharmacologic Intervention

Periodic follow-up central DXA on the same machine is recommended for following patients on pharmacologic therapy. The testing interval varies from 6 to 24 months depending on the clinical situations. Sequential bone density testing using central DXA may be useful, and is generally recommended in monitoring drug therapy for the treatment of osteopenia or osteoporosis. Ideally, such testing should be performed on the same machine as the pre-treatment bone density and no more than every 12 to 24 months. A frequency as often as every 6 to 12 months may be indicated in the case of glucocorticoid treated patients or those on suppressive doses of thyroid hormone. Other patients at risk for accelerated bone loss include women at early menopause or those who have discontinued estrogen and are not on another bone protective agent*. The lumbar spine and the total proximal femur have the highest reproducibility and are the preferred sites for monitoring therapy. Changes in BMD should only be reported as significant if they exceed the "least significant change" for the DXA center. Stability or increase in BMD indicates successful therapy. A significant decline in BMD may require further investigation.⁴ A significant decrease in BMD on therapy may be due to:⁴

- Poor drug adherence
- Improper medication administration technique in the case of bisphosphonates
- A missed secondary cause of osteoporosis (e.g., hyperparathyroidism, malabsorption)
- Inadequate calcium intake
- Untreated Vitamin D deficiency
- A true treatment failure due to the drug itself
- Malabsorption of orally administered drugs

Physical Medicine and Rehabilitation

Physical medicine and rehabilitation can reduce disability, improve physical function and lower the risk of subsequent falls in members with osteoporosis. Rehabilitation and exercise can improve function and the ability to carry out daily activities. Psychosocial factors also strongly affect functional ability of those with osteoporosis who have already suffered fractures.⁶ Providers should:

- Evaluate and consider the member's physical and functional safety as well as psychological and social status, medical status, nutritional status and medication use before prescribing a rehabilitation program.
- Evaluate the member and current medication to consider possible interactions and risk for altered mental status. Intervene as appropriate.
- Provide training for the performance of safe movement and safe activities of daily living, including posture, transfers, lifting and ambulation in populations with or at high risk for osteoporosis. Prescriptions for assistive device for improved balance with mobility should be given as appropriate.
- Implement steps to correct underlying deficits when possible (e.g., improve posture and balance and strengthen quadriceps muscles to allow a person to rise unassisted from a chair; promote use of assistive devices to help with ambulation, balance, lifting and reaching).
- Evaluate home environment for risk factors for falls and intervene as appropriate.
- Based on the initial condition of the member, provide a complete exercise recommendation that includes weight-bearing aerobic activities for the skeleton, postural training, progressive resistance training for muscle and bone strengthening, stretching for tight soft tissues and joints and balance training.
- Advise members to avoid forward bending and exercising with trunk in flexion, especially when twisting.
- As long as principles of safe movement are followed, walking and daily activities, such as housework and gardening, are practical ways to contribute to maintenance of fitness and bone mass. Additionally, progressive resistance training and increased loading exercises, within the parameter of the person's current health status, are beneficial for muscle and bone strength. Proper exercise may improve physical performance/function, bone mass, muscle strength and balance, as well as reduce the risk of falling.
- Avoid long-term immobilization and recommend partial bed rest (with periodic sitting and ambulating) only when required and for the shortest periods possible.
- In members with acute vertebral fractures or chronic pain after multiple vertebral fractures, the use of trunk orthoses (e.g., back brace, corset, posture training support devices) may provide pain relief by reducing the loads on the fracture sites and aligning the vertebra. However, long-term bracing may lead to muscle weakness and further de-conditioning.

Related WellCare Guidelines

In addition to the information contained in this document, please reference the following CPGs: *Fall Risk Assessment (HS-1033)*. Information related to prevention can be found in the following age-specific Preventive Health CPGs: *Adult (HS-1018)* and *Older Adult (HS: 1063)*.

NOTE: Clinical Policies can be accessed by going to www.wellcare.com – select the Provider tab, then “Tools” and “Clinical Guidelines”.

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Medical Policy Committee Approval History

Date	History and Revisions by the Medical Policy Committee
6/7/2018	<ul style="list-style-type: none"> • Approved by MPC. No changes.
8/18/2017	<ul style="list-style-type: none"> • Approved by MPC. Included Care Management section.
8/19/2016	<ul style="list-style-type: none"> • Approved by MPC. Updated recommendations from national organizations (ACOG, AACE).
8/7/2014	<ul style="list-style-type: none"> • Approved by MPC. Inserted HEDIS and STAR metrics.
7/31/2014	<ul style="list-style-type: none"> • Approved by MPC. Included updated information based on the National Osteoporosis Foundation and the American Congress of Obstetrics and Gynecology.
7/5/2012	<ul style="list-style-type: none"> • Approved by MPC. Inserted USPSTF recommendation.
12/1/2011	<ul style="list-style-type: none"> • New template design approved by MPC.
7/2010	<ul style="list-style-type: none"> • Approved by MPC.