

# **POSITION PAPER ON OSTEOPOROSIS, BONE DENSITOMETRY, and TREATMENT OF OSTEOPOROSIS (January 2004)**

## **I. Purpose:**

The purpose of this document is to provide a brief overview of osteoporosis, the diagnostic criteria, indications for bone densitometry, and position of the Ohio Bureau of Workers' Compensation regarding the payment for diagnosis and treatment of this condition.

## **II. Overview:**

Osteoporosis is a medical condition characterized by a reduction in bone mass resulting in weakening of the bone and increased risk of fracture particularly of the vertebra, hip, and wrist. It is estimated in the United States that it affects 10 million individuals and another 18 million individuals are at risk. Of these over 80 per cent are women.<sup>1</sup>

Osteoporosis is frequently categorized as primary or secondary osteoporosis. Primary osteoporosis is associated with menopause, advancing age, and "idiopathic osteoporosis" that may be seen in premenopausal women and middle-aged men. Secondary osteoporosis is caused by certain medical conditions or treatments that prevent either attainment of peak bone mass or enhance bone loss. Diseases commonly associated with increased risk of developing generalized osteoporosis in adults include (1) hypogonadal states, (2) endocrine disorders such as Cushing's syndrome, hyperparathyroidism, thyrotoxicosis, insulin-dependent diabetes mellitus, acromegaly, and adrenal insufficiency, (3) nutritional and gastrointestinal disorders, (4) rheumatologic disorders including rheumatoid arthritis and ankylosing spondylitis, (5) hematologic disorders and malignancy such as multiple myeloma, lymphoma, leukemia, and malignancy-associated parathyroid hormone-related (PTHrP) production, (6) several inherited disorders, and (7) other disorders such as immobilization, chronic obstructive pulmonary disease, pregnancy and lactation, scoliosis, multiple sclerosis, sarcoidosis, and amyloidosis.<sup>2</sup> Medications that may be associated with osteoporosis include glucocorticosteroids and adrenocorticotropins, gonadotropin-releasing hormone agonists, immunosuppressants, cytotoxic drugs, anticonvulsants (Phenobarbital, phenytoin), aluminum, long-term heparin use, long acting parenteral progesterone, supraphysiologic throxine doses, tamoxifen, and total parenteral nutrition.<sup>3</sup> Of these, glucocorticosteroids are the most important and most commonly used. Environmental factors that appear to be associated with increased risk of osteoporosis include cigarette smoking, sedentary lifestyle, and probably alcoholism. Physical activity (exercise or work) increases bone density particularly in younger aged individuals and is considered part of treatment for or prevention of osteoporosis.

Bone mineral density is a measurement of bone mass which is believed to account for approximately 70% of bone strength. This measurement was selected by the World Health Organization (WHO) in 1994 to be used as the basis for the diagnosis of osteoporosis. The bone mineral density is expressed as T-scores or Z-scores. A T-score is the number of standard deviations above or below the average bone mineral density of

young healthy white women. One standard deviation is believed to be equal to approximately 10-12% variation in bone density. The Z-score is the number of standard deviations above or below the average bone mineral density of age and gender-matched controls. According to WHO, the following diagnostic categories are defined based on bone mass measurement:

“Normal: bone mineral density is within 1 standard deviation of a young normal adult woman. (T-score above -1.0)

Low Bone Mass (Osteopenia): Bone mineral density is between 1 and 2.5 standard deviations below that of a young normal adult woman. (T-score between -1.0 and - 2.5).

Osteoporosis: Bone mineral density is below 2.5 standard deviations of a young normal adult woman. (T-score below -2.5)”<sup>4</sup>

Of the various techniques to measure bone mass, dual energy x-ray absorptiometry (DXA) is the most widely used and best validated device. While peripheral sites such as the wrist can be used, the lumbar spine and hip are the most common and recommended sites as predictors of future fractures. Other techniques such as quantitative computer tomography (QCT), peripheral DXA measurements, or qualitative ultrasonometry (QUS) are less available and less commonly used.

FDA-Approved indications for BMD Tests include:

- Estrogen deficient women at clinical risk of osteoporosis
- Vertebral abnormalities on x-ray suggestive of osteoporosis (osteopenia, vertebral fracture)
- Glucocorticoid treatment equivalent to  $\geq 7.5$  mg of prednisone with duration of therapy  $> 3$  months
- Primary hyperparathyroidism
- Monitoring response to an FDA-approved medication for osteoporosis
- Repeat BMD evaluations at  $> 23$ -month intervals, or more frequently, if medically justified.<sup>2</sup>

According to the National Osteoporosis Foundation, therapy to reduce fracture risk in women should be initiated if:

- BMD T-scores is below -2.0 by central DXA with no risk factors
- BMD T-scores is below -1.5 by central DXA with one or more risk factors
- A prior vertebral or hip fracture.

In addition patients should be counseled on the importance of calcium, vitamin D, and exercise as part of the treatment.

### **III. Application to Workers' Compensation in Ohio**

*Ohio Revised Code (ORC) 4123.01 (C)* states “Injury includes any injury, whether caused by external accidental means or accidental in character and result, received in the course

of, and arising out of, the injured employee's employment. *Injury* does not include:...(2) Injury or disability caused primarily by the natural deterioration of tissue, an organ, or part of the body."

*ORC 4123.01 (F)* states "*Occupational disease* means a disease contracted in the course of employment, which by its causes and the characteristics of its manifestation or the condition of the employment results in a hazard which distinguishes the employment in character from employment generally, and the employment creates a risk of contracting the disease in greater degree and in a different manner from the public in general."

Regarding BWC payment of services, the Ohio Administrative Code (OAC) 4123-6-25 (A) states "medical supplies and services will be considered for payment when they are medically necessary for the diagnosis and treatment of conditions allowed in the claim, are causally related to the conditions allowed in the claim, and are rendered by a health care provider." In addition, Ohio Administrative Code (OAC) 4123-7-02 states "medical or other services to be approved for payment must be rendered as a direct result of an injury sustained or occupational disease contracted by a claimant in the course of and arising out of employment for which the claim was allowed by an order of the bureau of workers' compensation or of the industrial commission, or for which the claim was recognized by a self-insuring employer."

Based on these definitions, osteoporosis is not an injury or occupational disease since it is for the most part a natural deterioration of tissue due to advancement of age and hormonal changes. A review of the causes of primary and secondary osteoporosis fails to show any occupational exposure or activity that would increase the likelihood of an individual to develop osteoporosis as an occupational disease. While an individual with osteoporosis may sustain a fracture while on the job or performing a work activity, the workplace did not cause the osteoporosis and the fracture does not aggravate it. If present, the osteoporosis more likely than not would be a major contributor to the fracture. Therefore, osteoporosis can not be recognized as an occupational disease.

It is possible that an injured worker could accelerate the development of osteoporosis through the use of medications used to treat another allowed condition in the claim. Based on review of the medical conditions and medications associated with the development of osteoporosis, this would most likely be the use of glucocorticoids of sufficient amounts and duration. (Glucocorticoid treatment equivalent to  $\geq 7.5$  mg of prednisone per day and duration of therapy  $> 3$  months). This dosage would most likely be used to treat individuals with significant pulmonary and possibly dermatologic conditions. These dosages and durations would not commonly be used for musculoskeletal conditions. Individuals receiving cytotoxic drugs or immunosuppressants may also be more likely to develop such acceleration of osteoporosis.

Whether or not diagnostic testing should be authorized to determine whether osteoporosis is present or treatment of osteoporosis would be appropriate the Miller Criteria described by The Ohio Supreme Court ruling in *State ex rel. Miller v. Indus. Comm.* 71 Ohio St. 3d 229, 643 N.E.2d 113 (1994) should be considered. In that decision, the Court ruled a three pronged test should be applied for the authorization of medical services. The three prongs or criteria are (1) are the medical services "reasonably related to the industrial injury, that is the allowed conditions"? (2) are the services "reasonably necessary for treatment of the industrial injury"? and (3) is "the cost of such service medically

reasonable”)? For an older individual who may have incurred a back, hip, or wrist injury, more likely than not, routine x-rays will diagnose any fracture present. If x-rays are negative and the individual remains symptomatic, the most common diagnostic study to determine the presence of an occult fracture would be a bone scan. Therefore, bone densitometry would not be reasonably necessary to determine if a fracture is present. If an individual of appropriate age and risk factors has an injury including a fracture that may have occurred at the workplace, it most likely is medically appropriate to determine whether osteoporosis is present in the individual. However, this determination and possible treatment is directed toward a medical condition that is not allowed in the claim and not causally related to the workplace. Any treatment at that time would be prophylactic (preventive) to avoid fracture in the future. Therefore, more likely than not, such treatment does not meet the Miller Criteria for authorization.

#### **IV. Recommendations**

1. Osteoporosis does not appear to have a direct causal relationship to work injury or work exposures.
2. Authorization of services for diagnosis or treatment of osteoporosis should not be commonly considered or approved.
3. It may be appropriate to monitor for osteoporosis individuals (usually with Bone Density Measurements or DEXA scans) who are being treated for other allowed conditions if that condition or the treatment of the allowed condition is associated with the development of osteoporosis. For example, monitoring of individual who is of appropriate age and treated for allowed condition with prednisone at doses greater than 7.5 mg per day for more than 3 months. These decisions must be made on a case by case basis.
4. Due to the long term nature, treatment of osteoporosis should require an additional allowance to the claim. Expert Independent Medical Examination may be necessary to determine causal relationship.
5. If the claim is allowed for osteoporosis, appropriate treatment would include medication and monitoring as recommend by guidelines such as those from the National Osteoporosis Foundation.

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<sup>1</sup> “Osteoporosis as a National Public Health Priority”, A Position Statement of American Academy of Orthopaedic Surgeons, 1999.

<sup>2</sup> Lindsay R and Cosman F., “Osteoporosis” in Harrison’s Principles of Internal Medicine 15<sup>th</sup> Edition, McGraw-Hill, 2001, pp 2226-2237.

<sup>3</sup> “Physician’s Guide to Prevention and Treatment of Osteoporosis” National Osteoporosis Foundation, 2003.

<sup>4</sup> “Assessment of Bone Mineral Density and Fracture Risk” National Institutes of Health Osteoporosis and Related Bone Diseases-National Resource Center, Volume 4, April 2002.