

MEDICARE COVERAGE OF DXA BONE DENSITY TESTING IN MEN JUNE, 2009

Introduction

Hypogonadism in men is a condition in which the body does not produce enough of the male sex hormone testosterone. Testosterone deficiency affects 4-5 million men in the United States and places these individuals at risk for developing osteoporosis. Women after menopause have low levels of estrogen and are similarly considered hypogonadal. Currently, the Centers for Medicare and Medicaid Services (CMS) provides coverage under the Medicare program for bone mass measurement using dual energy x-ray absorptiometry (DXA) scans for postmenopausal women because estrogen deficiency results in an increased risk for osteoporosis. Despite the clear association of male hypogonadism with low bone density and osteoporosis¹, and the fact that effective treatments are available^{1,2,3,4,5}, Medicare does not provide coverage for bone mineral densitometry testing in these individuals. The current paradigm leads to men with osteoporosis being underdiagnosed and undertreated, resulting in significant morbidity and mortality and cost to

society^{2,6,7}. The Endocrine Society advocates widening the scope of Medicare coverage to include bone density scans for men with hypogonadism equal to that afforded to women.

Background

Bone mineral density, measured by dual-energy x-ray absorptiometry, is an excellent predictor of the risk for fractures in both men and women^{1,3,5,8}. Some local Medicare carriers do include coverage of bone density scans for men with hypogonadism. Nationally, Medicare currently provides coverage for DXA scans in men when an individual has been previously diagnosed with osteoporosis, primary hyperparathyroidism, vertebral bone fracture, or osteopenia of the spine, or in certain other situations. Regrettably, this means that most men found to have osteoporosis are diagnosed only after a hip or spine fracture has already occurred.

A five-year study done by Kaiser Permanente in California tracked more than 625,000 male and female patients over the age of 50 in Southern California who had specific risk factors for osteoporosis and/or hip fractures. The implementation of a number of initiatives including increasing the use of bone density testing (DXA scans) and anti-osteoporosis medications reduced the hip fracture rates by 37 percent⁶. There are currently four FDA approved medications for osteoporosis in men^{1,4,5} (alendronate, risedronate, zoledronic acid and

¹ Eberling, PR. Osteoporosis in Men. *N Engl J Med* 2008; 358: 1474-82.

² Feldstein AC, et al. The near absence of osteoporosis treatment in older men with fractures. *Osteoporosis International* 2005; 16(8):953-62.

³ Lim, LS, et al. Screening for Osteoporosis in the Adult U.S. Population ACPM Position Statement on Prevention Practice. *AM J Prev Med* 2009; 36(4):366-375.

⁴ National Institutes of Arthritis and Musculoskeletal and Skin Diseases. Osteoporosis Overview. The U.S. Department of Health and Human Services. Cited 2 November 2008.

<http://www.niams.nih.gov/bone/hi/overview.htm>.

⁵ Qaseem, A., et al. Pharmacologic Treatment of Low Bone Density or Osteoporosis to Prevent Fractures: A Clinical Practice Guideline from the American College of Physicians. *Annals of Internal Medicine* 2008; 149:404-415.

⁶ Dell, et al. Osteoporosis Disease Management: The Role of the Orthopaedic Surgeon *J Bone Joint Surg Am.* 2008; 90:188-194.

⁷ Schouseboe, JT, et al. Cost-effectiveness of Bone Densitometry Followed by Treatment of Osteoporosis in Older Men. *Journal of the American Medical Association* 2007; 298(6):629-637.

⁸ Qaseem, A., et al. Screening for Osteoporosis in Men: A Clinical Guideline from the American College of Physicians. *Annals of Internal Medicine* 2008; 148:680-684.

teriparatide), all of which increase bone mineral density similarly to their effects in women.

Because of the limited Medicare coverage of DXA testing, osteoporosis continues to be an under-recognized problem in men. Osteoporosis goes untreated in most men, even those who present with spine and hip fractures^{1,2}. It is estimated that 2 million men have osteoporosis and another 8-13 million have osteopenia, increasing their risk for osteoporotic fracture. In the United States, 2 million osteoporotic fractures occur each year; 29% of these occur in men. Men account for more than 80,000 hip fractures in the United States each year^{4,9}. The rate of morbidity and mortality as a result of osteoporotic fractures is significantly higher among men than among women^{1,2}.

Men diagnosed with hypogonadism have high rates of osteoporosis and are at greater risk for fracture. It is estimated that 1/3 of men with osteoporosis have hypogonadism¹. There are a variety of conditions which cause male hypogonadism, including tumors of the hypothalamus or pituitary gland, inflammatory diseases or infectious diseases which affect the testes and even normal aging. Medications can also cause hypogonadism. Hypogonadism is the intended therapeutic effect of androgen deprivation therapy, the most common medical treatment for prostate cancer. Men with prostate cancer treated with androgen deprivation have been shown to be at increased risk for low bone mass and hip fracture^{10,11}. Approximately one third of the estimated 2 million prostate cancer survivors in the United States are currently receiving one of these therapies¹⁰. There are no data that demonstrate that treatment of hypogonadal men with testosterone alone will prevent fractures. In fact, in many men with

prostate cancer, testosterone is contraindicated. Considerable controversy regarding the treatment of elderly men with testosterone exists, making it imperative to check bone mineral densities to assess the need for other pharmacological agents specifically used for osteoporosis.

Considerations

In 2005, osteoporosis-related fractures in men were responsible for an estimated \$4.3 billion in health care costs. By 2025, experts predict that these costs will rise to approximately \$6.3 billion⁹. To help reduce the high costs associated with fractures in the elderly population, preventive bone density tests for men with low testosterone levels should be included as a national coverage requirement under Medicare Part B. Studies have documented the cost effectiveness of bone mineral density testing in older men with no prior history of osteoporosis^{6,7,8}. With the recent availability of a generic preparation of the bisphosphonate alendronate, coverage of bone mineral density testing is likely cost effective—for men as young as 70 years even without the presence of hypogonadism.

As men with hypogonadism are more likely to have osteoporosis, it is imperative that consideration be given to Medicare coverage of bone density testing in order that osteoporotic fractures can be prevented in this most susceptible group.

Position

The Endocrine Society is concerned that men at risk for osteoporosis because of a diagnosis of hypogonadism have limited access to important preventive DXA scans to measure bone mineral density. Therefore, the Society recommends:

- That coverage under the Medicare program for DXA scans be extended to men with hypogonadism in a way that is consistent with coverage for other beneficiaries at clinical risk for osteoporosis.

This position statement is endorsed by the National Osteoporosis Foundation.

⁹ National Osteoporosis Foundation. Osteoporosis Fast Facts. Cited 7 July 2009.

<http://www.nof.org/osteoporosis/diseasefacts.htm#cost>

¹⁰ Shahinian, VB et al. Risk of fracture after androgen deprivation for prostate cancer. *N Engl J Med* 2005; 352:154-164.

¹¹ Smith, MR. Osteoporosis in Men with Prostate Cancer: Now for the Fracture Data. *Journal of Clinical Oncology* 2008; 26(27):4371-4372.