

**July 8, 2024**

Michael J. Barry, M.D. Chair  
U.S. Preventive Services Task Force  
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Dear Chair Barry and Task Force Members

On behalf of the Bone Health and Osteoporosis Foundation (BHOFF), I am submitting comments to the Draft Recommendation Statement: *Osteoporosis to Prevent Fractures: Screening*. BHOFF **does not** believe USPSTF came to the right conclusions in this draft. We are disappointed that USPSTF did not take advantage of the opportunity to enhance its screening recommendations both for men and women, essentially leaving recommendations unchanged from current ones. We urge the Task Force to review and modify its Draft Recommendation Statement before it is finalized and we provide specific suggestions, background and evidence for USPSTF consideration.

The BHOFF is the nation's leading resource for patients, health care professionals and organizations seeking up-to-date, medically sound information and program materials on the causes, prevention, diagnosis and treatment of osteoporosis. Established in 1984 as America's only voluntary, nonprofit health organization dedicated to reducing the widespread prevalence of osteoporosis, the foundation has grown to include a network of diverse stakeholders that support its goals to increase public awareness and knowledge, educate physicians and health care professionals, and support research activities concerning osteoporosis and bone health related areas.

### **Background**

Unlike many other debilitating conditions, outcomes in osteoporosis for both women and men can be significantly improved without substantial investment in research, new breakthrough therapies, or new legislative and/or regulatory provisions. Therapeutic and lifestyle modification interventions, including prescription medications, can change disease trajectory and significantly reduce the risk of osteoporotic fracture. Unfortunately, under-utilization of Dual-energy X-ray absorptiometry (DXA) as a primary prevention tool means that for many patients, the first sign of osteoporosis is a fracture. Most patients remain undiagnosed and unaware of both their increased risk of a future fracture and the availability of FDA-approved therapies to reduce that risk.

According to a 2021 analysis by independent actuarial firm Milliman commissioned by the BHO, Medicare beneficiaries (both in traditional Medicare and Medicare Advantage) suffered approximately 2.1 million osteoporotic fractures in 2016.<sup>i</sup> Notably, osteoporosis has significant consequences for men as well as women. Of the 1.3 million Medicare beneficiaries covered by traditional Medicare who had at least one osteoporotic fracture in 2016, an estimated 912,000 were women and 381,000 were men. The mortality rate for osteoporotic fracture patients is over three times that of the general Medicare FFS beneficiary population. Nearly one in five Medicare FFS beneficiaries died within 12 months following a new osteoporotic fracture. This accounted for approximately 245,000 deaths among Medicare FFS beneficiaries covered by Parts A and B or Part A alone who suffered an osteoporotic fracture in 2016. And the outcomes are deadly for both men and women. Of these, about 154,000 were female and 91,000 were male. Beneficiaries with a hip fracture had the highest mortality of any osteoporotic fracture: 30% died within 12 months of the fracture.<sup>ii</sup>

Annual allowed medical costs to Medicare for beneficiaries in the 12-month period beginning with the new osteoporotic fracture were more than twice their costs in the year prior to their fracture, with incremental annual allowed medical costs for those with an osteoporotic fracture of \$21,564 per beneficiary covered by both Medicare Parts A and B in 2016.<sup>iii</sup> The incremental annual medical costs in the year following a new osteoporotic fracture increased 263% for skilled nursing facility (SNF) services compared to the year prior to the fracture, accounting for nearly 30% of the total incremental annual medical cost. Beneficiaries suffering a subsequent fracture within three years of an initial fracture accounted for an estimated \$5.7 billion in Medicare FFS direct costs. Actual total costs are significantly higher as these estimates do not include costs related to the loss of productivity, absenteeism, non-skilled home and nursing home care, or prescription drugs.<sup>iv</sup>

While too few women are screened for osteoporosis, **even fewer men receive necessary screening.** The 2021 Milliman report referenced above found that **only 5% of men** and 9% of women using traditional Medicare received a Bone Mineral Density (BMD) test within six months following a new osteoporotic fracture. The human and financial impact of the failure to adequately screen for and thus intervene and prevent osteoporotic fractures is enormous. 41,900 Medicare FFS beneficiaries with osteoporotic fractures became institutionalized in nursing homes within three years of a new fracture. Osteoporotic fracture patients have three times the annual rate of new fractures within a year as compared to the overall Medicare FFS population. Over 4% (approximately 56,800 Medicare FFS beneficiaries) with an osteoporotic fracture became newly eligible for Medicaid within three years.<sup>v</sup> The total annual cost for osteoporotic fractures among Medicare beneficiaries was \$57 billion in 2018.<sup>vi</sup> Absent health system changes to more effectively detect, diagnose and treat the chronic, progressive disease of osteoporosis, annual costs of fragility fractures are expected to grow to over \$95 billion in 2040).<sup>vii</sup> While fractures are more common in women, **men tend to have worse outcomes after**

**fracture.**<sup>viii</sup> A meta-analysis of 24 studies, including data from 578,436 women and 154,276 men, estimated the excess mortality risk after hip fracture for both men and women.<sup>ix</sup> The 1-year excess mortality in men after hip fracture at age 80 years is 18%, more than twice the excess mortality in women (8%) of the same age at fracture. Data from the prospective Baltimore Hip Fracture study<sup>x</sup> confirmed men are more likely to die after hip fracture than women.<sup>xi</sup>

There are osteoporosis medications approved by the FDA based on efficacy/effectiveness and safety for use in men, including bisphosphonates (alendronate, risedronate and zoledronic acid), denosumab, teriparatide, and abaloparatide. A 2017 systemic review and meta-analysis of 22 clinical trials found that FDA approved bisphosphonates substantially reduce osteoporotic fractures among men<sup>xii</sup>. Denosumab has fracture reduction data in men as well. In men with nonmetastatic prostate cancer receiving androgen deprivation therapy, denosumab significantly decreased the incidence of new vertebral fractures at 12, 24, and 36 months (by ~85%, ~69%, and ~62% respectively).<sup>xiii</sup> New evidence has emerged that treatments for osteoporosis are equally effective in men as in women. Denosumab has fracture reduction data in men as well. In men with nonmetastatic prostate cancer receiving androgen deprivation therapy, denosumab significantly decreased the incidence of new vertebral fractures at 12, 24, and 36 months (by ~85%, ~69%, and ~62% respectively). A [newly published study by Keaveny et al](#) which reviewed the records of 250,000 patients found that “the reduction in risk of hip fracture associated with treatment did not differ between the sexes.” The expert authors conclude that “these results demonstrate that treating osteoporosis in patients at high risk of hip fracture should reduce the risk of hip fracture similarly in both sexes.” [The study](#) further found:

*“Addressing that evidence gap, we found that in this patient population — which was confirmed to be at high risk of hip fracture by multiple different metrics (BMD, FRAX, and femoral bone strength) — the reduction in risk of hip fracture associated with standard-of-care osteoporosis treatment was at least as large for men as for women. Including hundreds of hip-fracture cases, this is perhaps the largest ever study of treatment effects on risk of hip fracture, and the only one to directly compare treatment effects between the sexes.”*

### **Screening Recommendations**

BHOF recommends that USPTF update its recommendations for osteoporosis screening to parallel the recommendations BHOF has published. BHOF recommends that the following people receive bone density testing:

- ✓ Women age 65 years and older
- ✓ Men age 70 years and older
- ✓ Anyone who has broken a bone after age 50 years

- ✓ Women age 50-64 years with risk factors\*
- ✓ Men age 50-69 years with risk factors\*

\*Examples of risk factors for osteoporosis and fractures include family history of osteoporosis and/or fracture, frequent falling, vitamin D deficiency, smoking, excessive alcohol intake, malabsorption and other high risk medical conditions (diabetes, rheumatoid arthritis, etc.), and use of high-risk medications, such as prednisone.

These recommendations reflect the expert guidance provided in the [Clinicians Guide to the Prevention and Treatment of Osteoporosis](#). As stated in the Guide:

*“Who should be tested? The decision to perform initial bone density measurement should be based on an individual’s fracture risk profile and skeletal health assessment. Measuring bone density is not indicated unless test results will influence treatment and management decisions. The BHOFF recommends screening densitometry in women aged  $\geq 65$  years and men aged  $\geq 70$  years, younger postmenopausal women aged 50–64 years, and men aged 50-69 years with risk factors for osteoporosis. The BHOFF also recommends BMD testing for women and men with fracture(s). These recommendations are in concert with those of the ISCD and Endocrine Society clinical practice guidelines for osteoporosis in men<sup>xiv xv</sup>. Routine bone density measurement is not recommended for children or adolescents and is not routinely indicated in healthy young men or premenopausal women unless there is a significant fracture history or specific risk factors for bone loss (such as glucocorticoid use). Recommended screening densitometry in men BHOFF (formerly NOF) and other societies recommend BMD testing in men to inform clinical decisions regarding treatment. This includes men aged 70 years and older regardless of risk factors, men aged 50–69 years with clinical risk factors for fracture, and men who have broken a bone at age 50 years or older. In addition, men with conditions or on treatments associated with bone loss or low bone mass should be considered appropriate candidates for BMD screening (in its 2018 report, the US Preventive Services Task Force [USPSTF] confirmed the utility of BMD by DXA in predicting fracture in both women and men, but they found insufficient evidence at that time to recommend routine testing in men) [22, 65].”*

BHOFF strongly believes that updating USPSTF guidelines for osteoporosis screening for women and men are warranted by both the great human and financial toll incurred as a result of osteoporosis and osteoporotic fractures and the proven benefits of increased screening.<sup>xvixvii</sup> We know that USPSTF guidelines will bring insurance coverage of (and thus access to) screening to more people who would benefit from it. Also, importantly, it will increase health professional recommendations for screening and lead to fewer devastating osteoporotic fractures.

Thank you for your consideration of our views and recommendations. If you have any questions regarding our submission or these issues, please do not hesitate to contact me at [cgill@bonehealthandosteoporosis.org](mailto:cgill@bonehealthandosteoporosis.org).

Sincerely,

Claire Gill

CEO

Bone Health and Osteoporosis Foundation

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<sup>i</sup> [Medicare cost of osteoporotic fractures: 2021 updated report \(milliman.com\)](#)

<sup>ii</sup> Ibid.

<sup>iii</sup> Milliman, supra.

<sup>iv</sup> Ibid.

<sup>v</sup> Ibid.

<sup>vi</sup> Lewiecki EM, et al. Hip fracture trends in the United States, 2002 to 2015. *Osteoporosis Int.* 2018; 29: 717-722

<sup>vii</sup> Ibid.

<sup>viii</sup> Cawthorn, P. *Gender Differences in Osteoporosis and Fractures*. Clin Orthop Relat Res. 2011 January 25

<sup>ix</sup> Haentjens P, Magaziner J, Colon-Emeric CS, Vanderschueren D, Milisen K, Velkeniers B, Boonen S. Meta-analysis: excess mortality after hip fracture among older women and men. *Ann Intern Med.* 2010;152:380–390.

<sup>x</sup> Hawkes WG, Wehren L, Orwig D, Hebel JR, Magaziner J. Gender differences in functioning after hip fracture. *J Gerontol A Biol Sci Med Sci.* 2006;61:495–499.

<sup>xi</sup> Cawthorn, supra

<sup>xii</sup> Nayak S, Greenspan SL. Osteoporosis treatment efficacy for men: A systematic review and meta-analysis. *J Am Geriatr Soc.* Mar 2017;65(3):490-5.

<sup>xiii</sup> Smith MR, et al. *N Engl J Med* 2009;361:745-755.

<sup>xiv</sup> Watts NB, Adler RA, Bilezikian JP, Endocrine Society et al (2012) Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 97(6):1802–1822

<sup>xv</sup> International Society for Clinical Densitometry (2019) ISCD OFFICIAL POSITIONS - ADULT. Available at: <https://iscd.org/learn/official-positions/adult-positions/> Accessed October 2019

<sup>xvi</sup> Lewiecki EM, et al. Hip fracture trends in the United States, 2002 to 2015. *Osteoporosis Int.* 2018; 29: 717-722

<sup>xvii</sup> Milliman, supra.