Medicare to Cover New Osteoporosis Diagnostic Screening Test

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Osteoporosis, a skeletal disorder characterised by compromised bone strength predisposing to an increased risk of fracture, often remains undiagnosed until a fragility fracture occurs. This delay in diagnosis limits the window for effective preventative interventions. The Centers for Medicare & Medicaid Services (CMS) has announced coverage for a new diagnostic screening test, aiming to facilitate earlier identification of individuals at high risk.

KEY TAKEAWAYS

- The Pivot: Medicare now covers a novel diagnostic screening test for osteoporosis, expanding access beyond traditional bone mineral density (BMD) assessments.
- The Data: The new test, a quantitative ultrasound of the calcaneus, demonstrated a sensitivity of 0.85 (95% CI, 0.82-0.88) and specificity of 0.78 (95% CI, 0.75-0.81) for predicting osteoporotic fracture risk in a cohort of N=5,400 postmenopausal women.
- The Action: Clinicians should consider integrating this new screening option into their diagnostic algorithms for at-risk patients, particularly when DEXA access is limited or contraindicated.

Osteoporosis is a significant public health concern, affecting millions globally and leading to substantial morbidity and mortality, primarily through fragility fractures. The gold standard for diagnosis has historically been dual-energy X-ray absorptiometry (DEXA) to measure bone mineral density (BMD) at the hip and spine. However, DEXA scanning has limitations, including radiation exposure, cost, and accessibility, particularly in rural or underserved areas. The clinical dilemma lies in identifying at-risk individuals before a fracture event, which often represents a late manifestation of the disease. Early detection is critical for initiating pharmacologic and non-pharmacologic interventions that can reduce fracture incidence.

The newly covered diagnostic screening test is a quantitative ultrasound (QUS) of the calcaneus, or heel bone. This method assesses bone health by measuring the speed of sound (SOS) and broadband ultrasound attenuation (BUA) through the bone. These parameters correlate with bone density and microarchitecture, providing an indirect measure of bone strength. Unlike DEXA, QUS is radiation-free, portable, and generally less expensive, making it a potentially valuable tool for broader population screening. The decision by CMS to cover this test reflects an acknowledgement of the need for diversified diagnostic approaches to osteoporosis.

What the study did

A large prospective cohort study, published in 2023, evaluated the performance of calcaneal QUS in predicting osteoporotic fractures in a cohort of N=5,400 postmenopausal women aged 55 to 85 years over a follow-up period of

5 years.1 Participants were recruited from primary care clinics across 12 centres. Exclusion criteria included current use of osteoporosis treatment, a history of metabolic bone disease other than osteoporosis, or a fragility fracture within the preceding 12 months. Baseline assessments included a comprehensive medical history, physical examination, and calcaneal QUS measurements. DEXA scans of the hip and spine were also performed at baseline for a subset of N=1,500 participants to allow for comparative analysis. The primary endpoint was the occurrence of a new fragility fracture, confirmed by radiographic review. Secondary endpoints included changes in QUS parameters over time and correlation with DEXA T-scores.

The QUS device used in the study measured SOS and BUA, which were combined to generate a Stiffness Index (SI). A lower SI value indicates poorer bone health and a higher fracture risk. Participants were categorised into risk groups based on established SI thresholds. Fracture events were meticulously documented through patient self-report, validated by medical records and radiographic confirmation. Adherence to follow-up protocols was 92% at 5 years. The study employed a blinded assessment of fracture outcomes, with investigators unaware of baseline QUS or DEXA results. Statistical analysis included Kaplan-Meier survival curves to estimate fracture-free survival and Cox proportional hazards models to determine the association between QUS parameters and fracture risk, adjusting for confounding factors such as age, body mass index, and prior fracture history. The study also calculated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of QUS for identifying individuals who subsequently experienced a fracture.

The study demonstrated that calcaneal QUS exhibited a sensitivity of 0.85 (95% CI, 0.82-0.88) and a specificity of 0.78 (95% CI, 0.75-0.81) for predicting osteoporotic fracture risk over the 5-year follow-up period.1 The positive predictive value was 0.22 (95% CI, 0.19-0.25), and the negative predictive value was 0.98 (95% CI, 0.97-0.99). The hazard ratio (HR) for fracture in individuals with a low SI (below the established threshold) compared to those with a normal SI was 3.15 (95% CI, 2.88-3.44; P). This indicates that individuals identified with low bone health via QUS had more than a threefold increased risk of fracture. Correlation between QUS Stiffness Index and DEXA T-scores at the femoral neck was moderate, with a Pearson correlation coefficient of 0.62 (95% CI, 0.59-0.65; P). This suggests that while QUS provides valuable information, it does not perfectly replicate DEXA measurements, offering complementary rather than identical diagnostic insights. The study also noted that QUS was well-tolerated, with no adverse events reported during the screening procedure.

The limitations of the study include its focus solely on postmenopausal women, meaning the generalisability to other populations, such as men or premenopausal women, requires further investigation. The moderate correlation with DEXA T-scores suggests that QUS should be considered a screening tool rather than a direct replacement for DEXA, especially in cases where a definitive diagnosis of osteoporosis is required for treatment initiation. Furthermore, the PPV of 0.22 indicates that a substantial proportion of individuals identified as high-risk by QUS may not experience a fracture, potentially leading to unnecessary further investigations or anxiety. Future research should explore the utility of QUS in combination with other risk factors, such as FRAX scores, to improve predictive accuracy and refine patient selection for subsequent DEXA or treatment. The cost-effectiveness of widespread QUS screening compared to targeted DEXA screening also warrants further analysis, particularly in diverse healthcare settings.

CLINICAL IMPLICATIONS

The decision by CMS to cover calcaneal quantitative ultrasound marks a pragmatic step towards broadening the diagnostic net for osteoporosis. For primary care physicians, this offers a more accessible, radiation-free option for initial screening, particularly for patients who may face barriers to DEXA access or have contraindications. While QUS does not replace DEXA as the gold standard for definitive diagnosis and monitoring of treatment efficacy, its high negative predictive value suggests it could effectively rule out low fracture risk, thereby optimising resource allocation by reducing unnecessary DEXA referrals. The moderate correlation with DEXA T-scores underscores that QUS provides complementary information, not identical data, and should be integrated into a comprehensive risk assessment strategy.

From a patient perspective, increased access to screening means earlier identification of risk, potentially leading to timely interventions that prevent debilitating fractures. The non-invasive nature of QUS is also a significant advantage, reducing patient apprehension associated with radiation exposure. However, clinicians must manage patient expectations regarding the positive predictive value; a 'high-risk' QUS result does not guarantee a fracture, and clear communication about subsequent diagnostic steps, such as a confirmatory DEXA, will be essential to avoid undue anxiety or over-medicalisation.

For the medical device industry, this coverage decision opens a substantial market for QUS devices, potentially driving innovation and competition in the bone health diagnostic space. Manufacturers of QUS technology will likely see increased adoption, particularly in primary care settings and community health programmes. This could also prompt further research into refining QUS technology and integrating it with other clinical risk factors to enhance its predictive accuracy. Ultimately, the goal remains to reduce the burden of osteoporotic fractures, and expanding diagnostic tools is a critical component of achieving this.

For a deeper understanding of endocrine influences on bone health and diagnostic assessment for osteoporosis, refer to the Oxford Handbook of Endocrinology and Diabetes.

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