
Medical Policy



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***Current Policy Effective Date: 7/1/26**
(See policy history boxes for previous effective dates)

Title: Trabecular Bone Score

Description

A Trabecular bone score (TBS) is an index of bone microarchitecture derived from lumbar spine Dual Energy X-ray Absorptiometry (DXA), and it serves as an indirect measurement of trabecular bone quality.

Medical Policy Statement

The Trabecular Bone Score (TBS) is **experimental/investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes

Other codes (investigational, not medically necessary, etc.):

77089	77090	77091	77092
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Established

N/A

Notes:

- *Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.*
 - *Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.*
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Background

Trabecular Bone Score (TBS) measurements utilize a computer software application that is installed on dual X-ray absorptiometry (DXA) machines. The program takes the DXA image of the lumbar spine (low back) and creates a greyscale pixel image of the vertebral trabecular bone microstructure, which may provide information that is not captured from standard bone mineral density (BMD). Higher TBS values are associated with better skeletal microstructure, while lower TBS values are associated with weaker skeletal microstructure. TBS iNsight™ is an example of this technology.

According to the U.S. Food and Drug Administration (FDA) summary document (K152299), TBS iNsight™ is a software provided for use as a complement to both DXA analysis and clinical examination. It computes the AP spine DXA examination file and calculates the Trabecular Bone Score (TBS) that is compared to those of the age-matched controls. The TBS is derived from the texture of the DXA image and has been shown to be related to bone microarchitecture. TBS cannot be used to diagnose osteoporosis and should not be used alone to initiate treatment. It provides as an option an assessment of 10-year fracture risk, based on the World Health Organization's (WHO) Fracture Risk Assessment (FRAX) Tool, after adjustment for the TBS. The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and other medical conditions leading to altered trabecular bone microarchitecture, and ultimately in the assessment of fracture risk. The TBS score can assist the health care professional in monitoring the effect of treatments on patients across time.

Summary of Evidence

Evidence in the peer reviewed scientific literature evaluating Trabecular Bone Score (TBS) is lacking. The clinical utility in the medical management of the patient compared to standard currently available methods have not been scientifically determined. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. The following is a summary of the key literature to date.

Kim et al (2020) screened 7,192 eligible subjects from the Ansung cohort (South Korea), 1,165 women aged 45 to 76 years with available bone mineral density (BMD) and TBS data were enrolled in this study.¹ The study assessed their clinical risk factors for osteoporotic fractures and evaluated the predictive value of FRAX with or without BMD and TBS. During the mean follow-up period of 7.5 years, 99 (8.5%) women suffered major osteoporotic fractures (MOFs) and 28 (2.4%) experienced hip fractures. FRAX without BMD, BMD-adjusted FRAX, and TBS-adjusted FRAX were significantly associated with the risk of MOFs (hazard ratio [HR] per percent increase, 1.08; 95% confidence interval [CI], 1.03 to 1.14; HR, 1.09; 95% CI, 1.03 to 1.15; and HR, 1.07; 95% CI, 1.02 to 1.13, respectively). However, BMD-adjusted FRAX and TBS-adjusted FRAX did not predict MOFs better than FRAX without BMD based on the Harrell's C statistic. FRAX probabilities showed limited value for predicting hip fractures. The cut-off values of FRAX without BMD, FRAX with BMD, and FRAX with BMD adjusted by TBS for predicting MOFs were 7.2%, 5.0%, and 6.7%, respectively.

The authors concluded that FRAX with BMD and TBS adjustment did not show better predictive value for osteoporotic fractures in this study than FRAX without adjustment.

Mirzaei et al (2018) evaluated the clinical value of TBS on Fracture Risk Assessment Tool (FRAX) algorithm.² A total of 358 postmenopausal Iranian women (mean age 61.3 ± 9.5 years) tested for areal Bone Mineral Density (aBMD) and TBS, 184 osteopenic women were identified. Thoracolumbar spine X-ray done in all participants revealed twenty-one vertebral fractures. For the osteopenic group, FRAX and TBS adjusted FRAX (FRAX-TBS) were calculated and compared. A significant correlation was found between TBS and spine aBMD ($r = 0.50$, $p < .001$) and TBS and femoral neck aBMD ($r = 0.37$, $p < .0001$). A strong positive correlation was observed between aBMD adjusted FRAX and FRAX-TBS in predicting the risk of major osteoporotic fracture ($r = 0.90$, $p < .0001$), and hip fracture ($r = 0.97$, $p < .0001$). According to the area under the receiver operating characteristics curve, the predictive value of the three different models using aBMD, TBS, and combination of aBMD and TBS were similar (0.765, 0.776, and 0.781, respectively; $p = .19$). The proportion of the women needed treatment remained unchanged using FRAX or FRAX-TBS.

The authors concluded that the study showed no clinical benefit for TBS in postmenopausal women. Adding TBS data to aBMD or FRAX neither improved aBMD predictive value for vertebral fracture nor changed the decision on treatment based on FRAX.

Kuzma et al (2018) compared three risk assessment instruments-the FRAX, the TBS, and a TBS-adjusted FRAX score-in their ability, to predict future fragility fractures over a minimum of five years of follow-up among post-menopausal osteopenic women with no prior fragility fractures.³ The authors also sought to determine if more- versus less-stringent criteria were better when stratifying patients into higher-risk patients warranting osteoporosis-targeted intervention versus lower-risk patients in whom intervention would usually be deemed unnecessary. Over a mean 5.2 years follow-up, 18 clinical fragility fractures were documented among 127 women in the age 50 years and older (mean age = 66.1). On multivariate analysis utilizing regression models and Kaplan-Meier curve analysis, less-stringent criteria for the FRAX and TBS-adjusted FRAX were capable of predicting future fractures (with sensitivity/specificity of 83/31; 39/77 and 78/50% for TBS, FRAX and TBS-adjusted FRAX, respectively), while more-stringent criteria were incapable of doing so (with sensitivity/specificity of 56/60; 39/77 and 39/74 for TBS, FRAX and TBS-adjusted FRAX, respectively).

The authors concluded that TBS threshold alone was not a significant predictor of future fracture in their study. Adjusting the FRAX tool by incorporating the TBS may be useful to optimize the detection of post-menopausal osteopenic women with no prior fractures who warrant osteoporosis-targeted therapy.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

American Association of Clinical Endocrinology (AACE)/ American College of Endocrinology

The American Association of Clinical Endocrinology (AACE)/American College of Endocrinology (ACE) references trabecular bone score (TBS) values in the following recommendation-May 2020⁴

"Pharmacologic therapy is strongly recommended for patients with a T-score between -1.0 and -2.5 if the FRAX® (fracture risk assessment tool) (or if available, trabecular bone score [TBS]-adjusted FRAX®) 10-year probability for major osteoporotic fracture is $\geq 20\%$ or the 10-year probability of hip fracture is $\geq 3\%$ in the [United States] or above the country-specific threshold in other countries or regions (Grade A; BEL 1)" (Recommendation 22, p. 6).

Bone Health & Osteoporosis Foundation (BHOFF) / (previously known as National Osteoporosis Foundation (NOF): The BHOFF Clinician's Guide to Prevention and Treatment of Osteoporosis (LeBoff, et al., 2022) states:⁵

Trabecular bone score (TBS) is an assessment of how evenly or unevenly mineral is structurally distributed in trabecular bone. A TBS is generated from lumbar spine BMD images using software installed on a DXA machine. No additional scan time or radiation exposure is required. The TBS gray-scale texture model captures local differences in mineral concentrations, providing an index of bone microarchitecture that predicts fracture risk independent of BMD and FRAX® scores. TBS is correlated with BMD at spine and hip as well as with FRAX® risk projections for hip and major osteoporotic fracture. Adding TBS to

FRAX®, which is possible on late-model densitometry devices, increases the ability of FRAX® to predict fractures (TBS-adjusted FRAX®). TBS is most applicable to patients who have low bone mass, rather than those with osteoporosis according to BMD criteria, for whom treatment is already indicated.

U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force recommendations for TBS have been identified.

Regulatory Status

Assessment of fracture risk in patients using the trabecular bone score (TBS) is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

TBS iNsight™ received FDA 510(k) Premarket Notification clearance (K152299) on March 25, 2016. FDA product code: KGI.³

The predicate device Med-Imaps TBS iNsight™ was cleared under (K121716) on June 4, 2012.⁴

Government Regulations

National:

No National Coverage Decision on this procedure.

Local:

No Local Coverage Decision on this procedure.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov did not identify any ongoing or unpublished trails that would likely influence this review.

References

1. Kim H, Kim JH, Kim MJ, et al. Low predictive value of FRAX adjusted by trabecular bone score for osteoporotic fractures in Korean women: a community-based cohort study. *Endocrinol Metab (Seoul)*. 2020;35(2):359-366. doi:10.3803/EnM.2020.35.2.359
2. Mirzaei A, Jahed SA, Nojomi M, Rajaei A, Zabihyeganeh M. A study of the value of trabecular bone score in fracture risk assessment of postmenopausal women. *Taiwan J Obstet Gynecol*. 2018;57(3):389-393. doi:10.1016/j.tjog.2018.04.011
3. Kužma M, Hans D, Koller T, Nemethova E, Jackuliak P, Killinger, Resch H, Payer J. Less strict intervention thresholds for the FRAX and TBS-adjusted FRAX predict clinical fractures in osteopenic postmenopausal women with no prior fractures. *J Bone Miner Metab*. 2018;36(5):580-588. doi:10.1007/s00774-017-0864-1
4. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis-2020 update. *Endocr Pract*. 2020;26(Suppl 1):1-46. doi:10.4158/gl-2020-0524suppl.
5. LeBoff MS, Greenspan SL, Insogna KL, Lewiecki EM, Saag KG, et al. The Bone Health and Osteoporosis Foundation (BHOFF) – formerly the National Osteoporosis Foundation (2022) The clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2022 Apr 28. Epub ahead of print. Erratum in: *Osteoporos Int*. 2022 Jul 28.
6. FDA. TBSiNsight 2016 [K152299.pdf](#) accessed 3/3/26
7. FDA. TBS iNsight 2012 [k121716.pdf](#) accessed 3/3/26

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March, 2026, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/22	4/19/22		Joint policy established
7/1/23	4/18/23		Routine maintenance Vendor: NA (ky)
7/1/24	4/16/24		Routine maintenance Vendor: NA (ky)
7/1/25	4/15/25		Routine maintenance Vendor: NA (ky)
7/1/26	4/21/26		Routine maintenance Vendor: NA (jf/ky/fr) • Formatting changes made: ○ Sections rearranged for better flow ○ Added Description and Background separated ○ MPS edited ○ Note edited in coding section

Next Review Date: 2nd Qtr, 2027

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TRABECULAR BONE SCORE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.