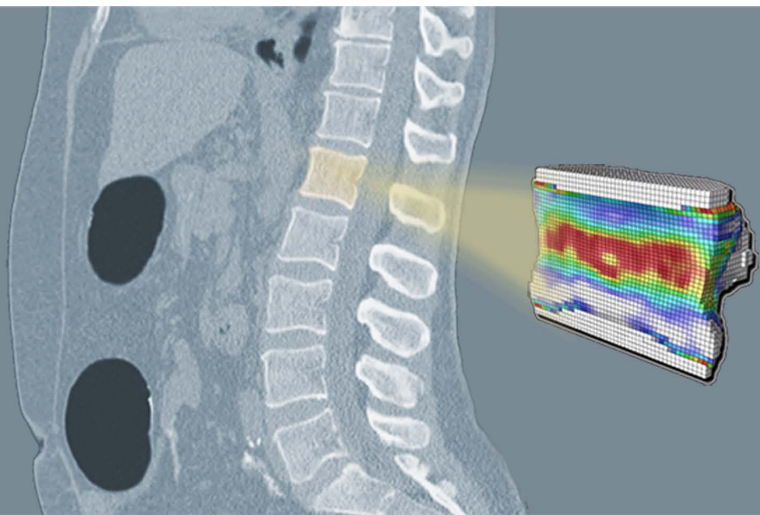


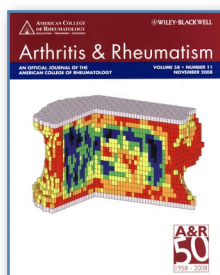
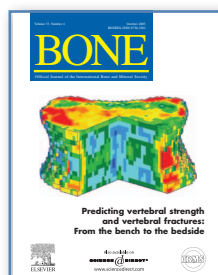
VirtuOst® BCT

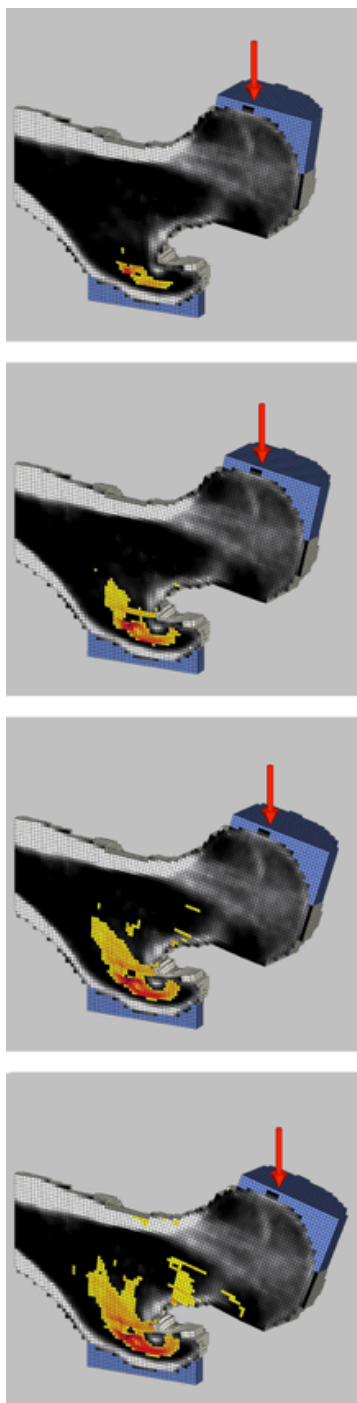
The virtual stress test for bone.

A new paradigm in the clinical assessment of osteoporosis, bone quality and fracture risk.



Provides Bone Strength + Bone Mineral Density + Fracture Risk Classification
Indicated by the FDA to Assess Fracture Risk, Identify Osteoporosis, and Monitor Therapy
Repurposes Routine Hip or Spine CT Scans • Reimbursed by Medicare, No Copay





ABOVE: Images show stages of a VirtuOst BCT virtual stress test on a patient's proximal femur. A sideways fall is simulated to determine the bone's breaking strength. Colored areas show tissue failure with red being the most severe.

The Science Behind VirtuOst® BCT

A Dual Approach for Identifying Osteoporosis — Bone Strength and BMD.

The U.S. Surgeon General defines osteoporosis as “a skeletal disorder characterized by compromised bone strength, predisposing to an increased risk of fracture.”^{1,2} VirtuOst BCT is the first FDA-cleared test to identify osteoporosis and assess fracture risk on the basis of compromised bone strength.³ By combining finite element analysis with bone biomechanics, VirtuOst BCT performs a virtual stress test that simulates a sideways fall on the hip or a compressive overload on the spine, to determine the functional breaking strength of the proximal femur or vertebral body. In addition, since bone mineral density (BMD) testing is the current standard for osteoporosis assessment,^{4,5} VirtuOst BCT also measures BMD. This dual approach yields a unique and comprehensive test for osteoporosis that is extensively validated and unsurpassed in accuracy.³

Capturing High-Risk Patients Missed by BMD. Most fragility fractures occur in patients with low BMD (osteopenia),⁶ who typically go untreated for fracture prevention. VirtuOst BCT's dual approach can identify a subset of these patients who, nonetheless, are at high risk of fracture due to compromised bone strength.^{3,7,8} Mechanistically, these patients may have small or unusually shaped bones, focally weak regions, or cortical-trabecular imbalance,³ elements of bone quality that are not detected by BMD.

Repurpose a Patient's CT Scan that Includes the Hip or Lower Spine

Despite clear guidelines on who should get screened for osteoporosis, most eligible patients do not get tested by DXA.²⁰ For the millions of screening-eligible patients each year who already undergo a hip- or spine-containing CT scan during their care for any medical indication, VirtuOst BCT can now repurpose that scan for BCT analysis. This “opportunistic” approach³ provides a convenient (*no extra patient visit*) and safe (*no extra radiation*) test that is both clinically impactful and cost effective compared to DXA.⁹

CT Scans Suitable for VirtuOst BCT. VirtuOst BCT can utilize most abdominal and pelvic CTs, chest and spine CTs, low-dose lung CTs, and whole-body PET/CTs.^{8,10–14,21} For CT scans acquired with IV contrast, BCT can be performed at the hip but not the spine. For patients without a suitable CT, a new CT can be ordered specifically for BCT. Depending on the available CT scan data, VirtuOst BCT assesses one proximal femur (preferably the left side) and/or one vertebral body from T12–L3 (preferably L1).

References: 1. Bone Health and Osteoporosis: A Report of the Surgeon General. U.S. Department of Health and Human Services, Office of the Surgeon General, Rockville, MD, 2004; 2. NIH Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy. JAMA 285:785–795, 2001; 3. Keaveny, Osteoporos Int 31:1025–48, 2020; 4. Kanis Osteoporos Int 17:527–534, 2006; 5. WHO Scientific Group on the Assessment of Osteoporosis at Primary Healthcare Level. World Health Organization, Brussels, Belgium, 2004; 6. Siris, Arch Intern Med 164:1008–12, 2004. 7. Kopperdahl, J Bone Miner Res 29:570–80, 2014; 8. Adams, J Bone Miner Res 33:1291–1301, 2018; 9. Pisu J Bone Miner Res, 34:1229–39, 2019;

Interpreting the VirtuOst BCT Results

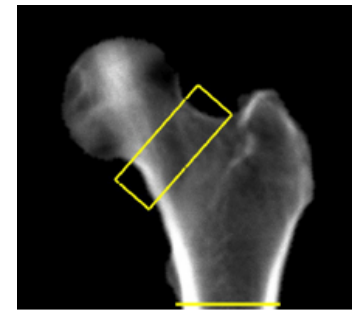
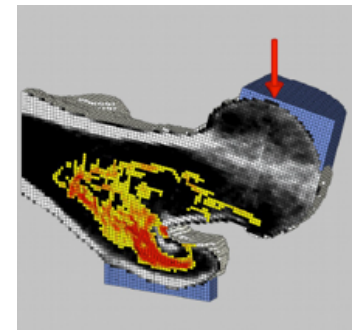
Bone Strength, BMD, and Fracture Risk Assessment. Based on established practice guidelines,^{4,5,15,16} VirtuOst BCT provides classifications for BMD and bone strength (see table) and the following overall fracture risk classifications:

- **Not Increased Risk:** normal BMD *and* normal bone strength
- **Increased Risk:** worst classification is low BMD or low bone strength
- **High Risk:** BMD-defined osteoporosis *or* fragile bone strength

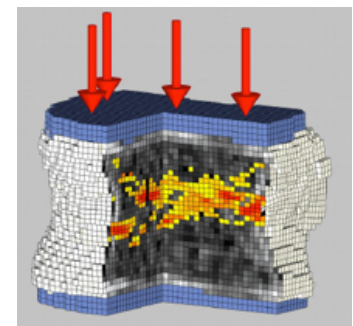
Who to Treat? Typically, an older patient testing positive for either fragile bone strength or BMD-defined osteoporosis is considered to have osteoporosis and be at high risk of fracture. Such a patient would be a candidate for therapeutic treatment.^{1-5,15,16} DXA confirmation is not necessary.³

	<u>SPINE</u>	<u>HIP</u>
	Bone Mineral Density (BMD)	
Women & Men	BMD* ≥ 120 mg/cm ³ Normal	BMD T-score** ≥ -1.0
	80 < BMD < 120 Low (osteopenia)	-2.5 < BMD T < -1.0
	BMD ≤ 80 Osteoporosis	BMD T-score ≤ -2.5
	Bone Strength (STR)	
Women	STR ≥ 6,000 N*** Normal	STR ≥ 4,000 N
	4,500 < STR < 6,000 Low	3,000 < STR < 4,000
	STR ≤ 4,500 Fragile Bone Strength	STR ≤ 3,000
Men	STR ≥ 8,500 N Normal	STR ≥ 5,000 N
	6,500 < STR < 8,500 Low	3,500 < STR < 5,000
	STR ≤ 6,500 Fragile Bone Strength	STR ≤ 3,500

* Vertebral trabecular volumetric BMD; T-scores are not used
 ** DXA-equivalent areal BMD T-score; use the lower T-score from the Femoral Neck or Total Hip regions
 *** Strength = force required to break the bone; force is measured in units of newtons (N)



TOP: Finite element model of the proximal femur after virtual stress testing to assess bone strength. **BOTTOM:** Hip image with the DXA-equivalent BMD-measured regions indicated in yellow.



TOP: Finite element model of a vertebral body. **BOTTOM:** Spine image with the BMD-measured region circled in yellow.

Bone Mineral Density Measurements. At the hip, VirtuOst BCT provides DXA-equivalent BMD T-scores^{7,8,10,11,21} that can be compared directly against DXA and used in risk calculators such as FRAX®.^{4,17} At the spine, it provides volumetric trabecular BMD, which is typically more effective than DXA in assessing vertebral fracture risk^{3,18,19} and for older and spinal fusion patients is less affected by degenerative changes.^{11,22}

Monitoring Responses to an Osteoporosis Drug Treatment. Medicare only reimburses DXA for such monitoring. If a patient tests positive by BCT and starts osteoporosis drug therapy, Medicare also covers a DXA test at that time to establish a baseline measurement for DXA-based monitoring.

Frequently Asked Questions Regarding Ordering and Reimbursement *

How do I order VirtuOst BCT for my patients? Place an order with your local BCT provider or order directly from the O.N. Diagnostics Medicare-enrolled centralized testing facility (for ordering instructions, visit ondiagnostics.com). For the latter, results are typically returned within one business day of O.N. Diagnostics receiving the CT scan.

Is VirtuOst BCT covered by Medicare? Yes. VirtuOst BCT is covered nationally by original ("traditional" or Part B) Medicare for bone density testing as a *"Bone Mass Measurement"* preventive service benefit, typically with waiver of copay and deductible. For other patients, since BCT is a new test, consult the patient's insurance plan to ensure coverage.

Which patients/conditions are covered? Medicare covers VirtuOst BCT as a reasonable and medically necessary *"Bone Mass Measurement"* diagnostic test for osteoporosis if the patient meets any of these four criteria:

- An **estrogen deficient woman** (post-menopausal) who is at risk for osteoporosis based on her medical history and other findings.
- An individual with **vertebral abnormalities**, as demonstrated by an X-ray to be indicative of osteoporosis, low bone mass, or vertebral fracture.
- An individual receiving (or about to receive) **glucocorticoid therapy** equivalent to an average of ≥ 5.0 mg of prednisone/day for ≥ 3 months.
- An individual with **primary hyperparathyroidism**.

Does an ICD code need to be included with an order? Yes, if a claim will be submitted for reimbursement, but no if the patient will self-pay. For Medicare reimbursement, all orders must include an ICD-10 code for any one of the above conditions; see sidebar for some example ICD codes provided by Medicare. For all orders, the ordering physician should document the medical necessity in advance of placing the order.

How frequently can VirtuOst BCT be ordered? Medicare typically allows for one bone density test every two years, regardless of the type of test used. In addition to VirtuOst BCT (CPT® 0554T-0558T), other types of bone density tests include DXA (CPT 77080, 77081, 77085), CT bone density (CPT 77078), and ultrasound (CPT 76977).

BCT Order Checklist

- ☐ Patient meets one of the four criteria for coverage.
- ☐ Relevant ICD code is specified.
- ☐ No other bone density test has been reimbursed within past 23 months.

ICD Coding Examples

Z78.0 for asymptomatic menopausal state.

Z87.310 for personal history of (healed) osteoporosis fracture.

Z79.5X for long term (current) use of inhaled (Z79.51) or systemic (Z79.52) steroids.

E21.X for hyperparathyroidism, primary (E21.0) or unspecified (E21.3).

* The information provided here is general reimbursement information only; it is not legal advice, nor is it advice about how to code, complete, or submit any particular claim for payment. It is always the provider's responsibility to determine and submit appropriate codes, charges, modifiers, and bills for the services that were rendered.