April 27, 2023

Gift Tee
Director, Division of Practitioner Services
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Electronically Submitted

Re: Procedural concerns regarding non-coverage of codes 0554T–0558T

Dear Mr. Tee:

The American College of Radiology (ACR), representing more than 41,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists is writing to express our concern about the decision by the Centers for Medicare and Medicaid Services (CMS) to retroactively remove CPT codes 0554T - 0558T (biomechanical computed tomography (BCT) analysis) from the National Coverage Decision (NCD) 150.3 Bone Density Studies. These CPT codes describe services used for determining bone density using the FDA-cleared bone densitometer. These CPT codes were originally added to the list of covered services by transmittals in May and August 2019[1] and subsequently removed, retroactive to 2019, by transmittals in September 2022[2] and March 2023.[3] ACR requests CMS reinstate coverage of CPT codes 0554T-0558T, retroactively to 2019, because these services meet the definition of bone mass measurements.

Brief background and summary of events
CPT codes 0554T – 0558T were included in the AMA's 2019 CPT codebook and added to the list of covered bone densitometers for the Bone Density Studies NCD. These codes are listed in the table below. CPT codes 0554T-0557T describe services using an FDA-cleared bone densitometer, the VirtuOst BCT test. CPT code 0558T describes a CT scan taken specifically for the purposes of BCT analysis. Since 2019, under the Physician Fee Schedule, these codes have been contractor priced. Additionally, four Medicare Administrative Contractors have local coverage articles that included these CPT codes as covered services.[4]

On November 23, 2022, in the HOPPS Final Rule for CY 2023, CMS discussed its revision of the status indicators for VirtuOst BCT. Referring to the September transmittal, CMS explained that "*we revised the status indicator for CPT codes 0554T-0558T to "E1" to indicate that the codes are non-covered because the services described by the codes do not meet Medicare's definition of bone mass measurements*" and

[1] CMS transmittals R4313CP and R236OTN
[2] CMS transmittal R11594CP
[3] CMS transmittal R 11884
[4] Local coverage articles A57132, A59040, A5780, and A53252.

cited the regulation for bone mass measurement at 42 C.F.R. § 410.31.[5] However, as with the September transmittal, CMS did not state why the codes did not meet the definition of bone mass measurements. The regulation merely states that bone mass measurement is a test to identify bone mass, detect bone loss, or determine bone quality, and shall be performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or with a bone sonometer system that has been cleared for marketing by the FDA.

On Feb 8, 2023, and March 1, 2023, CMS issued transmittals stating that the BCT codes should be removed from NCD 150.3 because they were *"added in error,"* and made this action retroactive to July 2019. Once again, CMS did not state why the definition of bone mass measurements was not met. More importantly, CMS did not state the "error" that was made.

The ACR disagrees with the premise that VirtuOst does not meet the definition of bone mass measurements. These services *do meet the definition* of bone mass measurements. The regulation (see link at Footnote 1) has four requirements that a device must meet to qualify as a bone mass measurement:

- Be a radiologic, radioisotopic, **or other procedure.**
- Be performed for the purpose of **identifying bone mass, detecting bone loss, or determining bone quality**.
- Be performed with either **a bone densitometer** (other than single-photon or dual-photon absorptiometry) or with a bone sonometer system that has been **cleared for marketing for this use by the FDA under 21 CFR part 807**,or approved for marketing by the FDA for this use under 21 CFR part 814.
- **Includes a physician's interpretation** of the results of the procedure.

The codes for VirtuOst BCT represent procedures that identify bone mass, detect bone loss, and determine bone quality; they are FDA cleared as bone densitometers,[6] and they are interpreted by physicians. CPT Code 0554T, which describes the entire VirtuOst procedure includes all these elements:

> Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone-mineral density, interpretation, and report.

Code Descriptors

Biomechanical computed tomography (BCT) Analysis

Code.	Effective Date	Descriptor
0554T	July 1, 2019	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density,

[5] eCFR :: 42 CFR 410.31 -- Bone mass measurement: Conditions for coverage and frequency standards.
[6] VirtuOST FDA clearance Information: 510(k) Premarket Notification (fda.gov); KGI Bone Densitometer product description is available at Product Classification (fda.gov)

		utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone mineral density, interpretation and report.
0555T	July 1, 2019	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data.
0556T	July 1, 2019	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density.
0557T	July 1, 2019	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; interpretation and report.
0558T	July 1, 2019	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis

Transparency through Public Notice and Comment Opportunities for Coverage and Policy Articles

The ACR and other specialty societies continue to engage with CMS' Coverage and Analysis Group and the Medicare Administrative Contractors (MACs) to improve public notice and comment opportunities for coverage and policy articles. The change in coverage status for CPT codes 0554T-0558T retrospective to July 2019 proves existing processes are not adequate. We believe these principles should be implemented to streamline processes to provide adequate notice and comment on changes discussed in national and local communications including:

- Articles that accompany both National and Local coverage determinations (NCDs and LCDs) and identify billing codes (e.g., Current Procedural Terminology (CPT) codes and International Classification of Diseases (ICD) codes) to designate procedures and diagnoses that are covered pursuant to the NCD or LCD inherently dictate coverage and should be subject to notice and comment.
- Articles accompanying draft LCDs should be issued at the same time as draft LCDs to allow for concurrent notice and comment.
- Other new articles, or any updates to existing articles reflecting non-routine changes in coding, such as the elimination of diagnosis or procedure codes that would have the effect of limiting coverage, should also be subject to notice and comment.

We think that a public notice period is warranted before any policy or article changes take effect on beneficiary access to care. This allows time to educate and prepare health care providers about these policy changes, especially when code changes have the effect of limiting coverage for Medicare beneficiaries.

Medicare Payment Concerns

In its latest policy guidance, CMS non-covers biomechanical computed tomography (BCT) analysis retroactive to July 2019. In addition, the March 2023 Change Request also indicates that contractors shall adjust any claims brought to their attention that were processed in error (CR 13070.8). The ACR seeks guidance from CMS on how healthcare providers should handle claims using these codes going forward. We believe that claims paid using these codes should not be adjusted unless there is concern that these services were not properly furnished. In addition, we request CMS rescind the transmittals that withdrew coverage for VirtuOst BCT (CPT Codes 0554T-0558T) as we believe these codes meet the definition of bone mass measurements. These codes should remain contractor priced under the Medicare Physician Fee Schedule. Additionally, four MACs still have local coverage policies on this clinical topic. In addition, these codes should be paid when submitted on outpatient claims. Changes in coding or coverage have an impact on coding, billing, and reimbursement operations and all changes should be instituted consistently and prospectively to allow facilities and group practices to adjust accordingly.

The ACR appreciates the opportunity to provide comments to CMS on concerns regarding the non-coverage of codes 0554T-0558T. We appreciate your attention to this important matter, and we look forward to your response to our concerns. We encourage CMS to continue to collaborate with physicians and the vendor community to initiate a process that includes stakeholder input to address issues related to code changes and coverage of bone mass measurements going forward so this situation will not arise in the future. The ACR looks forward to continued dialogues with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues with respect to radiology, please contact Alicia Blakey, Principal Economic Policy Analyst at ablakey@acr.org.

Respectfully Submitted,

William T. Thorwarth Jr., MD, FACR
Chief Executive Officer

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