

ICD-10-PCS Coding Request for Transthoracic Echocardiography with Computer-Aided Image Acquisition

Submitted by Caption Health

ICD-10 Coordination and Maintenance Committee
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Presenters

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Coding Issue

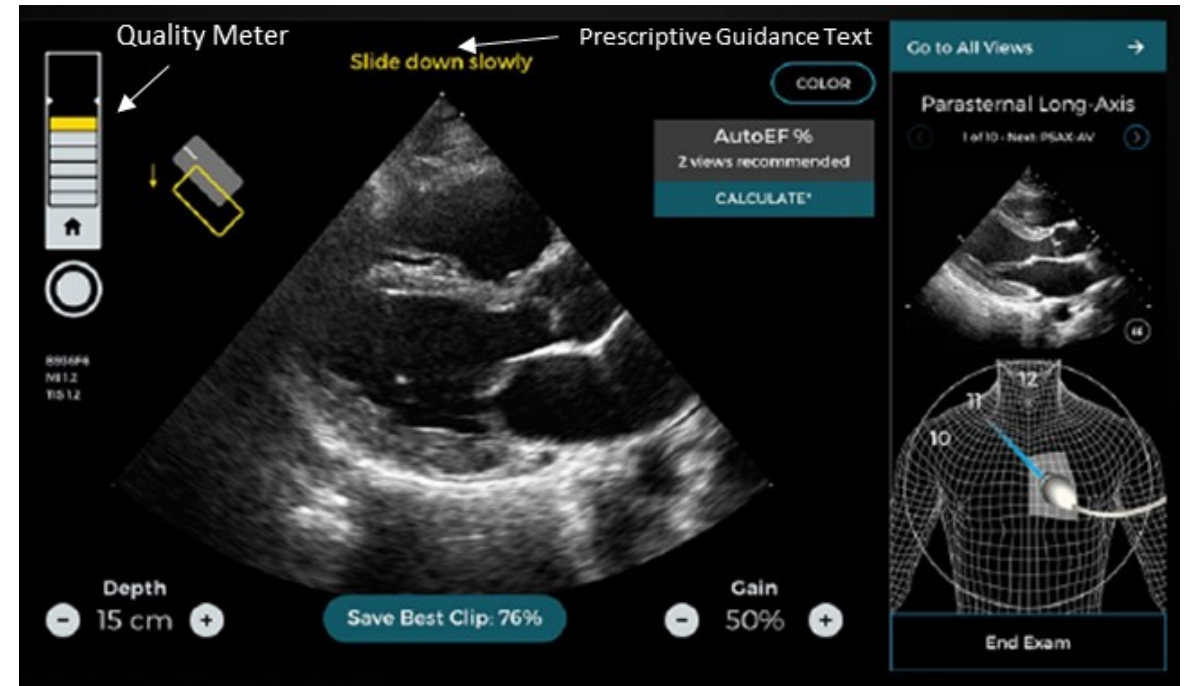
- There are currently no unique ICD-10-PCS codes to describe transthoracic echocardiography (TTE) with artificial intelligence (AI) - guided image acquisition
- Adding a unique ICD-10-PCS code would allow identification of TTE with AI-guided image acquisition
 - Unique code required to facilitate New Technology Add-on Payment (NTAP) implementation
- Caption Health has applied for NTAP for the Caption Guidance system, a AI-guided medical imaging acquisition system

Background on Caption Guidance System

- Caption Guidance is the only FDA-authorized AI-guided medical imaging acquisition system intended to assist medical professionals in the acquisition of cardiac ultrasound images.
 - Caption Guidance is software as a medical device (SaMD)
 - SaMD is software that has a medical purpose and is not part of a hardware medical device (i.e., ultrasound)
 - Caption Guidance received breakthrough designation by the FDA in 2018
- It is indicated for use in two-dimensional transthoracic echocardiography (2D-TTE) for adult patients, specifically in the acquisition of the following standard views:
 - Parasternal Long-Axis
 - Parasternal Short-Axis at the Aortic Valve
 - Parasternal Short-Axis at the Mitral Valve
 - Parasternal Short-Axis at the Papillary Muscle
 - Apical 4-Chamber
 - Apical 5-Chamber
 - Apical 2-Chamber
 - Apical 3-Chamber
 - Subcostal 4-Chamber
 - Subcostal Inferior Vena Cava

Overview of Caption Guidance Functionality

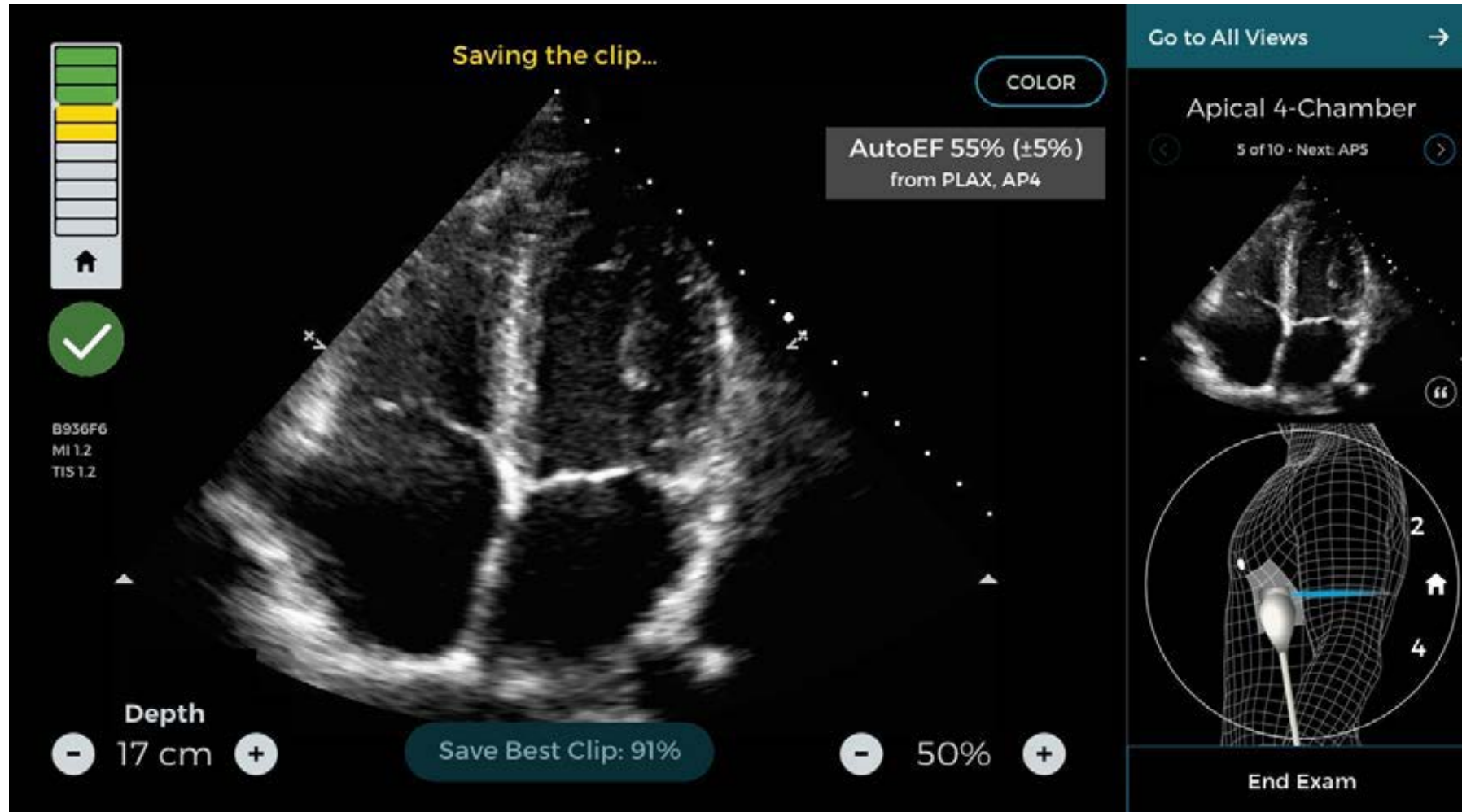
- As the medical professional is performing the TTE, the Caption Guidance system guides the user to acquire diagnostic echocardiographic images with the following features:
 - **Quality Meter.** Real-time feedback advises the user on the expected diagnostic quality of the resulting clip, such that the user can make decisions about further optimizing the quality using the Prescriptive Guidance feature.
 - **Prescriptive Guidance.** Direction to the user real-time to emulate how a sonographer would manipulate the transducer to acquire the optimal, diagnostic quality image.



Caption Guidance Functionality (Cont.)

- As the medical professional is performing the TTE, the Caption Guidance system guides the user to acquire diagnostic echocardiographic images with the following features:
 - **Auto-Capture.** This system triggers an automatic capture of a clip when the quality is predicted to be diagnostic, emulating the way in which a sonographer knows when an image is of sufficient quality to be diagnostic and records it.
 - **Save Best Clip.** Continually assesses clip quality while the user is scanning and, in the event that the user is not able to obtain a clip sufficient for auto-capture, the software allows the user to retrospectively record the highest quality clip obtained so far, mimicking the choice a sonographer might make when recording an exam.
- Images acquired during TTE are sent to PACS for review and interpretation by healthcare professional.

Caption Guidance Visual



Auto-Capture of AP4 view

Documentation in Medical Record

- The approach for documenting the procedure in the medical record will vary by provider
- Documentation Example
 - Internal procedure code established by the provider
 - Notes an echo with AI guided imaging in the order set in the medical record

The screenshot displays a medical record interface. At the top, a navigation bar includes tabs for 'Order and Order Set Search', 'Browse', 'Preference List', and 'Facility List'. Below this, a search bar contains the text 'ECHO AI'. A table of results is shown, with one entry highlighted in blue:

Name	Type	Ref List	Pr Code	POC
Echo AI Assisted	ECHO	NMH IP FACILITY IM...	ECHO1	

Below the table, a detailed form for 'Echo AI Assisted' is visible. The form includes fields for 'Priority' (STAT), 'Frequency' (ONE TIME), 'Starting' date (1/7/2021), 'First Occurrence' (Today 1503), and 'Scheduled Times' (01/07/21 1503). It also has a 'Comments' section with a '+ Add Comments (0)' button and a 'Last Resulted' field with the text 'No Creatinine Clearance results found.' At the bottom, there is a table for 'CC Results' with columns for 'Recipient', 'Modifier', and 'Add PCP'. The form concludes with 'Link Order' and 'Accept/Cancel' buttons.

Pivotal Study for Caption Guidance

- Caption Guidance pivotal study evaluated 240 study exams conducted by a medical professional without specialized echocardiography training
 - Five expert cardiologist readers assessed whether the patient study provided sufficient information
 - Studies by medical professionals with no scanning experience and studies by trained sonographers (control) were evaluated
- Data demonstrated that primary endpoints were met

#	Clinical Parameter	% of Scans of Sufficient Quality (MRMC CI)
1	Quality Visual Assessment of Left Ventricular Size	98.8% (96.7%, 100%)
2	Quality Visual Assessment of Global Left Ventricular Function	98.8% (96.7%, 100%)
3	Quality Visual Assessment of Right Ventricular Size	92.5% (88.1%, 96.9%)
4	Quality Visual Assessment of Non-Trivial Pericardial Effusion	98.8% (96.7%, 100%)

Summary

- There are currently no unique ICD-10-PCS codes that identify when AI-guided medical image acquisition is used
- Caption Health recommends creation of new procedure code to identify when AI-guided medical image acquisition is used during the TTE
- New code should be adopted independent of outcome of the NTAP application