



Avicenna.AI:

NTAP Information for Customers

The Centers for Medicare & Medicaid Services (CMS) recently approved a new technology add-on payment (NTAP) under the Medicare Inpatient Prospective Payment System (IPPS) for a radiological computer-assisted triage and notification software system that analyzes computed tomography angiogram (CTA) images of the brain acquired in acute settings, and which sends notifications to clinical team members when a suspected large vessel occlusion (LVO) has been identified to reduce time to treatment (85 Fed. Reg. 58432, 58636 (Sept. 18, 2020)). This NTAP payment enables hospitals to receive reimbursement above the usual Medicare Severity Diagnosis Related Group (MS-DRG) payment for a given patient when the technology is used, and the costs associated with the corresponding stay exceed a certain amount. In order to be eligible for the NTAP payment, the hospital must include the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) code 4A03X5D (Measurement of arterial flow, intracranial, external approach) on the claim form. The maximum NTAP payment is \$1,040 for fiscal year (FY) 2021.

Importantly, NTAP status is not applied only to the technology which requested the NTAP, but to any technology “substantially similar” to the applicant and for which use of the same ICD-10-PCS code is appropriate to describe the procedure. A technology is “substantially similar” to the applicant technology if: (1) it uses the same or similar mechanism of action to achieve a therapeutic outcome; (2) is assigned to the same MS-DRG; and (3) it is used in the treatment of the same or similar disease or patient population.

Avicenna.AI believes that there is a strong argument that the CINA[®] Head (CINA) triage solution is substantially similar to the applicant technology and that the same ICD-10-PCS code may be used

to describe the use of CINA[®]. With respect to the “substantially similar” analysis, like the applicant technology, CINA[®] is a radiological computer-aided triage and notification software indicated for use in the analysis of (1) non-enhanced head CT images; and (2) CT angiographies of the head. The solution is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings of head computed tomography (CT) images for intracranial hemorrhage (ICH) and large vessel occlusion (LVO). CINA uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH or LVO, and present notifications to clinicians in order to reduce time to treatment.

With respect to coding, the pertinent ICD-10-PCS code for this NTAP is 4A03X5D (Measurement of arterial flow, intracranial, external approach). This procedure code was created based on an application requesting the creation of a procedure code to describe the analysis of head and neck CT angiography using computer-aided triage and notification software. It is the provider’s responsibility to determine and submit the appropriate codes and modifiers for any service, supply, procedure or treatment rendered. As such, it will ultimately be the decision of the hospital as to whether it will use the code to bill for the utilization of CINA[®].

Because the company believes there are strong arguments that the use of CINA[®] is “substantially similar” to the use of the applicant technology, and the same ICD-10-PCS code appropriately describes the use of both technologies, we believe that an inpatient stay should be eligible for the NTAP regardless of whether the applicant technology or CINA[®] is used. Based on the code descriptor and application information, we are of the opinion that ICD-10-PCS code 4A03X5D could appropriately describe the use of CINA[®]. As noted above, the maximum NTAP payment for this procedure when applicable technology is used is \$1,040 for FY 2021.

CINA 1.0

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CINA[®], medical images analysis software, is a medical device manufactured by Avicenna.AI. This medical device is reserved for health professionals. This software has been designed and manufactured according to the EN ISO 13485 Quality management system. Read the instructions in the notice carefully before any use. Instructions for Use are available on <https://avicenna.ai/>

Manufacturer: Avicenna.AI (France).

Medical devices Class I following European Medical Device Directive 93/42/CEE.

Medical devices Class II following the Code of Federal Regulations of the United States of America 21CFR part 820 on Medical Devices.

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