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Artificial intelligence in radiology: Current trends and reimbursement

Artificial intelligence (AI) refers to computer algorithms that can mimic the characteristics of human intelligence, such as problem solving and learning. AI in radiology has been gaining ground in clinical practice and is being incorporated into daily practice in a variety of ways, including, but not limited to, large vessel occlusion, intracranial hemorrhage (ICH) and pulmonary embolism.

Historically, AI software was not widely used in radiology because many false-positives led to clinician distrust. Despite technological advances, trust issues remain, exacerbated by radiology rarely being black and white. Additionally, it is common for radiologists to assess various factors before reaching a "final" impression of images (and that impression may also have a level of uncertainty).

The aim of AI software is to help reduce interpretation errors and increase confidence in interpretations. However, some AI models can introduce greater uncertainty in the interpretation process, especially if the software's interpretation of the scan is discordant with the radiologist's initial interpretation.

Who will pay for AI?

There is no clear indication how this technology will be paid for and ultimately reimbursed by payers. Currently, approximately 21 radiology-related medical devices and algorithms have been approved by the U.S. Food and Drug Administration (FDA). More importantly, the Centers for Medicare & Medicaid

Magellan Healthcare clinical leaders continually review imaging trends and needs in light of current medical concerns, available literature, and society and Centers for Disease Control and Prevention recommendations and guidelines. This document is a summary of our latest findings. Please consult references for detailed information.

Services (CMS) recently approved reimbursement for these FDA-approved AI devices and algorithms via the Medicare Coverage of Innovative Technology pathway, which consists of two possible routes for reimbursement. Payment may come through the Medicare Physician Fee Schedule (MPFS) or the Inpatient Prospective Payment System (IPPS). If the MPFS route is chosen, the reimbursement mechanism would be the Current Procedure Terminology (CPT®) codes, which are maintained by the American Medical Association. If the IPPS route is chosen, the Diagnosis Related Groups (DRGs) and New Technology Add-on Payment (NTAP) will be the mechanism for reimbursement.

The IPPS pathway

In September 2020, CMS granted reimbursement for Viz.ai's Viz LVO (formerly known as ContaCT), AI-driven triage software for large-vessel occlusion, through the NTAP pathway. Since CMS' approval of Viz LVO for NTAP, other large-vessel occlusion AI software developers, such as RapidAI, Aidoc and Avicenna.AI, have applied for NTAP status from CMS. The NTAP program was initially introduced in 2001 with the intent to help provide support for up-and-coming medical therapies for patients enrolled in Medicare. To be approved for the NTAP program, the following criteria must be met:

1. The proposed technology must be new (<3 years old) and not based on another technology.
2. The proposed technology is not currently covered under the existing DRG.
3. The proposed technology must demonstrate a considerable advantage over already covered technologies (i.e., outcome data).

To share the financial risk between Medicare and hospitals providing these new technologies, CMS increased payment to 65% of the lesser of (1) the cost of the new medical service or technology or (2) the amount by which the costs of the case exceed the standard DRG payment.

IPPS is only available for three years, and it remains unclear if CMS will make DRG adjustments for these approved new technologies. CMS has historically lowered NTAP reimbursement following the initial year of approval. A critical point to remember is one of the criteria to be approved via the NTAP pathway is the technology must not substantially duplicate existing technologies. This raises the question of whether CMS will consider additional AI-driven algorithms that improve workflow a new technology and grant approval through the IPPS pathway.

The MPFS pathway

In 2020, CMS finalized a new ophthalmology CPT code, IDx-DR, the first of its kind for AI. IDx-DR uses AI to analyze retinal camera images for diabetic retinopathy screening. The relative value unit of this AI code/reimbursement is based on its ability to function independently without physician input (CPT code relative value units are based on two major components, physician work and practice expense.). In significant contrast, AI in radiology is mainly considered a support function to the radiologist instead of wholly independent. Whether the IDx-DR CPT code can be applied similarly to radiology or more along the lines of normal work for a specific procedure remains to be determined. Furthermore, in radiology, AI algorithms may ultimately result in more physician time, like what occurred with computer-aided detection in mammography.

Future payment alternatives

As healthcare shifts to a value-based payment system, AI may serve as a valuable tool for radiologists and imaging reimbursements. An example of this is the Merit-based Incentive Payment System model, which is the predominant pathway through which radiologists are reimbursed. Another possibility is an alternative payment model where AI algorithms could predict future disease risk based on imaging examination results. This could decrease overall cost of care and improve patient outcomes, leading healthcare systems to reimburse for this type of tool.

AI and large vessel occlusion strokes

The first AI product to be approved via the NTAP program for large vessel occlusion (LVO) strokes was Viz LVO. Since the 2018 FDA approval of the Viz LVO software to aid in the detection of LVO strokes, several studies have demonstrated improved triage of patients with LVO strokes with resultant improved patient outcomes and reduced length of stay.

Strokes are the number one cause of long-term disability in the United States. Treatments such as endovascular thrombectomy/thrombolysis for LVO strokes are effective, but they are time sensitive. The Viz LVO software automatically analyzes computed tomography angiography (CTA) of the brain of patients suspected of stroke to identify LVOs. Scans enter the radiologist's queue for reading and are simultaneously processed by the AI software. If an LVO is detected by the AI software, that study is flagged for the radiologist and sent directly to the on-call stroke team, allowing them to make a treatment decision or guide the team to further investigate. This alert has resulted in an average 52-minutes faster diagnosis than current practices.

AI and stroke: Is AI noncontrast computed tomography comparable to magnetic resonance imaging?

Magnetic resonance imaging (MRI) with diffusion-weighted sequences is considered the reference standard in evaluating for early ischemia. However, the lack of availability of MRI is a limitation. As computed tomography (CT) is often readily available and takes less time to image, it has become the standard imaging modality when evaluating acute cerebral ischemia. One critical limitation of CT, when contrasted with MRI, is the estimation of the degree of infarction on CT as the density variations of the involved brain parenchyma can be very subtle and could be further complicated by prior vascular lesions, as well as normal variants. Such subtle changes are often not appreciated by the human eye. A recent retrospective study by Qiu et al trained the AI system on patients who had both an MRI and CT (within 1 hour of each other) using the diffusion MR images to train the CT-based AI. They subsequently tested another set of CT scans with the trained AI model and compared them with diffusion MRI and found that machine learning software can identify subtle changes and patterns on CT with high accuracy. As such, noncontrast-enhanced CT scans of patients with acute ischemic stroke aided with this AI technology may ultimately rival information obtained with either CT perfusion or MRI. The study concluded that the AI software algorithm demonstrated promise in not only identifying, but also measuring, infarction on baseline noncontrast-enhanced CT scans and could transition into the clinical realm.

AI and cerebral hemorrhage

Considered the standard of care in the assessment of acute stroke and head trauma, noncontrast CT of the head is the most common emergent imaging study requested for neurological conditions. In trauma patients, as well as those at risk for an acute stroke prior to thrombolytic use, early diagnosis of acute intracranial hemorrhage is critical for improving patient outcomes. Radiology-support AI systems can evaluate head CT studies within seconds of its completion and immediately flag hemorrhages to alert radiologists or other clinicians (e.g., trauma or stroke teams), and to reprioritize the interpretation of the exam.

In preliminary studies, the software showed similar accuracy to interpreting radiologists in identifying hemorrhage type, precise localization and hemorrhage volume, allowing accurate assessment for interval changes on follow-up studies. This technology has been explored and utilized in small sizes in outpatients with significant benefit. Arbabshirani et al demonstrated an AI algorithm can successfully prioritize radiology worklists to reduce time to diagnosis of new outpatient ICH by 96% (from 512 to 19 minutes) and may also identify subtle ICH overlooked by radiologists.

Can AI help in the diagnosis of pulmonary embolism (PE)?

The diagnosis of PE is multifaceted, utilizing clinical presentation, D-dimer testing and imaging. Studies have shown the earlier a PE is identified, the better the patient's outcome. Weikert et al found the AI algorithm in their study correctly identified 215 of 232 exams positive for PE (sensitivity 92.7%, 95% confidence interval (CI)), and 1,178 of 1,233 exams negative for PE (specificity 95.5%; 95% CI). The false-positive scans encountered were contrast agent-related flow artifacts, pulmonary veins and lymph nodes. In a more recently published retrospective study, Ben Cheikh et al utilized an AI algorithm approved by the FDA and European Conformity and found the AI algorithm detected 219 suspicious PEs, of which 176 were true PEs, including 19 true PEs missed by radiologists. The study also noted the accuracy, specificity and positive predictive value were significantly higher for radiologists compared with the AI, except in the subcohort of scans with poor-to-average contrast bolus quality, which is typically challenging for radiologists. The authors concluded the AI algorithm best served as a safety net, or second look, in emergency radiology practice due to high sensitivity and negative predictive value; thereby, increasing the self-confidence of radiologists. Furthermore, several studies have shown that AI utilization in CTA PE exams help clinicians to automatically prioritize exams with a high suspicion of PE and may serve as a secondary reading tool.

Conclusion

AI software is ubiquitous in life, and other industries have already used this technology under the watchful eyes of human operators. As the research and deep machine learning continue to evolve, application in various aspects of healthcare is almost certain. Magellan Healthcare will continue to review AI software and other technologies as they continue to advance, as well as reimbursement patterns, to reduce diagnostic errors to the greatest extent possible.

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