

Who Will Pay for AI?

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In 2020, the largest U.S. health care payer, the Centers for Medicare & Medicaid Services (CMS), established payment for artificial intelligence (AI) through two different systems in the Medicare Physician Fee Schedule (MPFS) and the Inpatient Prospective Payment System (IPPS). Within the MPFS, a new Current Procedural Terminology code was valued for an AI tool for diagnosis of diabetic retinopathy, IDx-RX. In the IPPS, Medicare established a New Technology Add-on Payment for Viz.ai software, an AI algorithm that facilitates diagnosis and treatment of large-vessel occlusion strokes. This article describes reimbursement in these two payment systems and proposes future payment pathways for AI.

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Development of artificial intelligence (AI) in radiology has been much more rapid than in other specialties in health care. As of early 2020, there were approximately 21 medical devices and algorithms related to radiology approved by the U.S. Food and Drug Administration (FDA), which represented about 72% of all FDA-approved AI devices and algorithms in health care (1). U.S. regulatory approval is the initial hurdle for adoption of AI in the United States. A much bigger hurdle for broader adoption of new technology is payment. As the largest U.S. health care payer, the Centers for Medicare & Medicaid Services (CMS) establishes payment policy, and private payers typically follow. In the past year, reimbursement for AI has been approved by CMS through two different payment pathways: the Medicare Physician Fee Schedule (MPFS) and the Inpatient Prospective Payment System (IPPS). A simplistic answer to the question “Who will pay for AI?” given these new payment proposals is “the government will, and private payers will follow.” Unfortunately, as with most things in the health care policy world, it’s complicated. This article will review the different CMS payment systems and the two AI payment proposals and discuss potential AI reimbursement in the future.

CMS Payment Systems

To provide a better understanding of the two AI payment proposals, review of the CMS payment systems may be helpful. CMS utilizes three different payment systems to reimburse health care services. Physician office payments are paid through the MPFS. Hospital outpatient services are paid through the Hospital Outpatient Prospective Payment System (HOPPS) (2,3). The hospital inpatient payments are made through the IPPS (2). CMS recently proposed a new coverage pathway that is dependent on FDA market authorization for breakthrough devices, called Medicare Coverage of Innovative Technology.

CMS has tools within each system to make payments (Figure). Within the MPFS, the tool is the Current Procedure Terminology (CPT) code set, maintained by the

American Medical Association (4). CPT is discussed further in this article as the basis for one of the AI payment models.

In the IPPS, CMS can use the Diagnosis Related Groups (DRGs) and New Technology Add-on Payment (NTAP) as ways to make payments. DRG is a classification system that standardizes prospective payments for acute care services by grouping classes of patients who are similar clinically and in terms of their consumption of hospital resources. DRG and NTAP will be discussed in detail in this article with regard to the Viz.ai software.

In HOPPS, CMS utilizes a combination of CPT codes and Healthcare Common Procedure Coding System (HCPCS) codes for payment. Although CPT codes describe procedures or services provided by physicians, HCPCS codes identify drugs, supplies, equipment, and nonphysician services not represented in CPT. The CPT and HCPCS codes are grouped into payment categories called Ambulatory Payment Classifications on the basis of the geometric mean cost. Detailed discussion of HOPPS is beyond the scope of this article but has been described before (5). Medicare Transitional Pass-through Payment (TPT) is an additional tool CMS uses for payment of medical devices within HOPPS. A device must have had recent FDA approval (within 3 years), be reasonable and necessary for diagnosis or treatment, and be integral to part of the service furnished. The TPT is intended to allow CMS to collect data and assign appropriate permanent codes and rates. Historically, only a few devices have qualified for TPT, with only six of 26 device applications in the past 4 years qualifying for TPT (6).

CMS released a proposed rule regarding its newer tool, Medicare Coverage of Innovative Technology, a pathway that provides Medicare payment for any technology the FDA has deemed as a breakthrough device (7). A breakthrough device must provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating human disease or condition and must offer a treatment option that no other cleared or approved alternatives provide.

Abbreviations

AI = artificial intelligence, CMS = Centers for Medicare & Medicaid Services, CPT = Current Procedural Terminology, FDA = Food and Drug Administration, HCPCS = Healthcare Common Procedure Coding System, HOPPS = Hospital Outpatient Prospective Payment System, IPPS = Inpatient Prospective Payment System, MIPS = Merit-based Incentive Payment System, MPFS = Medicare Physician Fee Schedule, MS-DRG = Medicare Severity Diagnosis Related Group, NTAP = New Technology Add-on Payment, PE = practice expense, RUC = Relative Value Scale Update Committee, TPT = Transitional Pass-through Payment

Summary

Sustained adoption of AI through the current reimbursement framework may be challenging in a fee-for-service environment. As value-based payment models mature, in which measuring improvement in quality becomes increasingly important at decreased costs, AI becomes a valuable tool for radiologists and health care systems.

Keywords

Computer Applications-General (Informatics), Technology Assessment

The payment coverage would last for 4 years. The details of this payment system have not been finalized, and CMS has solicited feedback on this proposed pathway (7,8).

Reimbursement through the NTAP

In September 2020, CMS granted reimbursement for ContactCT by Viz.ai, AI-driven triage software for large-vessel occlusion, through the NTAP pathway (8). Established in 2000, through the Medicare, Medicaid, and State Children's Health Insurance Program Benefits Improvement and Protection Act, NTAP is a supplemental payment to hospitals in the IPPS. Under the IPPS, hospitals receive a bundled payment for acute care services such as the costs of operating room, nursing, supplies, and laboratory and imaging services in a DRG (9). For example, Medicare Severity (MS)-DRG 20 is the code for "Intracranial vascular procedure with a principal diagnosis of hemorrhage with major complication or comorbidity." The fiscal year 2019 Medicare base payment rate for that DRG is \$63 691. The NTAP was created to encourage adoption of innovative technology by reimbursing hospitals for part of the cost of expensive new health care services that may not be accounted for in the DRG reimbursement (9).

Since the announcement of Viz.ai's NTAP status in the IPPS final rule, other large-vessel occlusion AI software developers such as RapidAI, Aidoc, and Avicenna have been granted NTAP status by CMS. To qualify for reimbursement under NTAP, a technology must meet three criteria: (a) The technology or medical service must be considered new and "not substantially similar" to existing technologies, (b) the technology is inadequately paid for under the existing DRG system, and (c) use of the technology must substantially improve clinical outcomes more than existing services or technology (10). The NTAP is equal to the lesser of 65% of the amount by which the total covered costs of the case exceed the DRG payment or 65% of the costs of the new technology (11). This formula requires Medicare and hospitals to share the financial risk of providing costly new technologies. The NTAP for each

patient is determined individually on the basis of CMS calculations, with a maximum reimbursement set at \$1040.

To understand how the NTAP works, three different scenarios are discussed on the basis of the assumption that the estimated cost of the technology is \$2000 in an MS-DRG that reimburses \$60 000. The maximum NTAP would be 65% of \$2000, or \$1300. This example has been adapted from a prior publication (9).

Scenario 1: No NTAP Is Paid

The cost for a particular case is \$50 000. Since the cost is less than the MS-DRG (\$60 000), no NTAP is paid.

Scenario 2: The Maximum NTAP Is Paid

If the cost of the case is \$70 000, the cost is greater than the MS-DRG payment. The NTAP is the lesser of either 65% of the cost of the technology (\$2000), which is \$1300, or the excess cost, \$10 000. In this case, the payment is \$1300, and the hospital will receive a total payment of \$61 300.

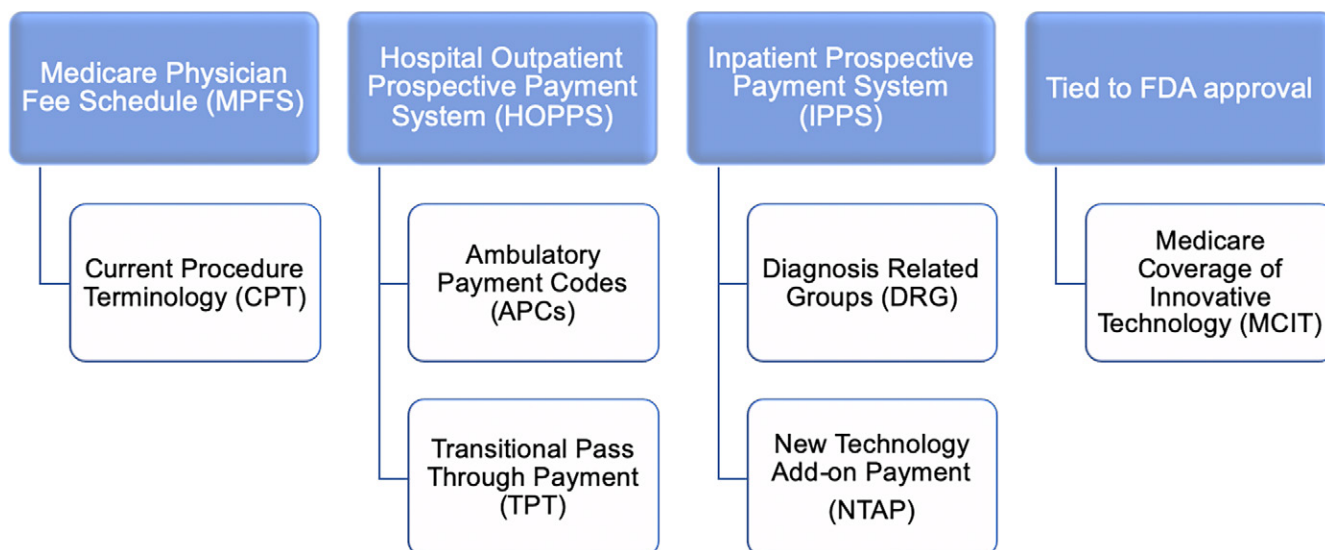
Scenario 3: The NTAP Is Less than the Maximum Reimbursement Allowed

In this scenario, the cost of the case is \$60 500. The excess cost is \$500, which is less than the maximum allowable NTAP of \$1300. The NTAP will be \$500, and the hospital will receive \$60 500.

Limitations of NTAP

Although Viz.ai's success with NTAP may signal the potential for AI reimbursement by CMS, enthusiasm should be tempered. This payment is only available for 3 years, and it is unclear how CMS would make permanent DRG adjustments for the new technology. Historically, CMS has lowered NTAP reimbursement after the initial year. An example of this reduction is the NTAP for HeartFlow's fractional flow reserve-CT product. This software is a noninvasive technology developed to test for coronary artery disease using a mathematical model of coronary physiology (12). Initially the NTAP maximum payment was set at \$1450, and in the following year, CMS dropped the NTAP to \$950 (13). Additionally, overall NTAP has historically been lower than what is estimated. CMS publishes estimated maximum financial impact for each NTAP-eligible technology in the final IPPS rule. Based on analysis from 2003 to 2006, only one of seven new technologies spent the maximum expected amount, and the remaining received lower than expected overall payments (9). An example is the NTAP for cardiac resynchronization therapy with defibrillation. CMS projected to spend \$341 million for NTAP and only spent \$128.1 million in fiscal year 2005, yielding a difference of \$212.9 million in the projected versus actual payment. The maximum add-on payment for this technology was \$16 263. The mean NTAP was \$3802, and median NTAP was \$1163 (9).

Recently, in the 2020 IPPS final rule, CMS revised the NTAP from 50% of the cost of the technology to 65% of the cost of technology (11). It remains to be seen whether this modification



Centers for Medicare & Medicaid Services tools for payment of health care services. FDA = Food and Drug Administration.

would truly provide the impetus for adoption and sustainability of AI in health care.

One final hurdle to consider is the NTAP requirement that technology must be considered not substantially similar to existing technologies. Would other AI-driven algorithms that improve clinical workflow be considered new technology?

AI in the PFS

On December 1, 2020, CMS finalized valuation of a new ophthalmology CPT code, IDx-DR, the first AI CPT code created by the American Medical Association CPT Editorial Panel. IDx-DR is an algorithm that analyzes images of the eye taken with a retinal camera. The images are uploaded to a cloud server, and the software provides two results: “more than mild diabetic retinopathy, refer to an eye care professional” or “negative for more than mild diabetic retinopathy; rescreen in 12 months” (5).

Valuations based on time-based activity that cost resources, proposed by the American Medical Association Relative Value Scale Update Committee (RUC), are finalized by CMS through an annual rule-making process and published in the MPFS. Description of the process for CPT code valuation is beyond the scope of this article and has been previously described (14). Briefly, the RUC makes recommendations for relative value unit values of CPT codes on the basis of two major components: physician work, measured in time and intensity, and practice expense (PE). The IDx-DR CPT code requires no physician work, and therefore the proposed valuation for the code is for PE alone.

PE is divided into two components: direct and indirect costs (15). Direct PE includes nonphysician clinical labor, such as technologist time, disposable medical supplies, and medical equipment, that can be attributable to a patient encounter. Indirect PE relates to such expenses as administration, rent, and other forms of overhead that cannot be attributed to any specific service. Examples of direct PE in radiology include cost of equipment such as CT scanners, contrast agents, and IV starter kits. Clinical staff resources, including technologist and nursing staff

time, are also examples of direct PE. Traditionally, software costs, similar to what would be associated with AI, are more challenging to attribute to a particular patient encounter. For example, subscription costs to analyze data in a cloud-based server may be difficult to attribute to direct PE. In the proposed rule, CMS stated that the RUC-recommended \$25 analysis fee for remote imaging be a fee that “constitutes a form of indirect PE and this cost is appropriately captured via the indirect PE methods as opposed to being included in separate direct PE input” (16). Despite public commenters stating that the analysis fee is linked to each patient encounter, CMS continues to struggle with allocating a subscription fee to direct PE, which results in substantially lower reimbursement for these codes. CMS finalized the reimbursement for IDx-DR as “carrier pricing,” meaning that coverage and pricing will be determined by local contractors (17).

Lessons Learned from IDx-DR

With the establishment of the IDx-DR code as the first AI CPT code, what lessons can be learned? First, the current structure of the PFS and methods of valuing PE cannot adequately capture the value of AI. Analysis performed on the cost of IDx-DR and estimated CMS technical reimbursement based on existing diabetic retinopathy codes predicted that the reimbursement would likely not cover the cost of the technology (18). CMS also acknowledged the inherent limitations in the 2021 Final Rule stating that “AI applications are not well accounted for in our PE methodology” (17).

This AI code is valued on the basis of an autonomous program where no physician work is performed. AI that augments physician work, as in the case with most imaging AI algorithms, likely will not be considered as a separate CPT code and would be considered simply as part of normal work within a procedure. Some AI algorithms may even require more physician time, similar to what was experienced with computer-aided detection in mammography (19). Even if the CPT panel revised codes, and the RUC revalued procedures to account for AI, valuation of procedures is based on the “typical” patient scenario, that is, what happens more

than 50% of the time. Nuanced increases in physician time to use AI algorithms for specific clinical scenarios likely would not meet the threshold for typicality. Given CMS's acknowledgment of the complexity of AI applications in the PFS and subsequent carrier pricing of the first AI code, IDx-DR, reimbursement in this payment system will continue to be a challenge.

Who Else Will Pay?

As health care moves toward value-based payments, where value is defined by improvement in quality while maintaining costs, maintaining quality at decreased costs, or improving quality at decreased costs, AI becomes a valuable tool for radiologists (20). The passage of the Medicare Children's Health Insurance Program and Reauthorization Act of 2015 placed physicians on a pathway toward value in two programs: the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (21,22). MIPS scores physicians in four areas, including cost, quality, interoperability, and improvement activities and remains the predominant pathway through which radiologists are reimbursed. Physicians report three of the four categories into MIPS to receive bonus payments or penalties on the basis of their performance (23). The cost category does not require clinician reporting and is scored by CMS on the basis of administrative claims data (24). The quality category remains one of the most important performance categories for radiologists because most are exempt from promoting interoperability, and many radiologists do not meet the threshold for the existing cost measures.

While there are many ways for reporting into MIPS, end-to-end electronic reporting is the approach favored by CMS (20,25). End-to-end electronic reporting refers to the use of automated software to aggregate measurement data, calculate measures, perform filtering of measurement data, and submit electronically to CMS via a web interface (25). AI is the natural foundation for any quality reporting, with its ability to mine data eliminating the manual burden of extracting data and calculating metrics (20). In the short term, AI that could automate extraction of quality metrics in an imaging report could benefit a radiologist's performance in MIPS, bolstering bonus payments. In this scenario, radiologists should be willing to pay for AI, as it provides value to their practice. In the long term, AI could facilitate the development of meaningful metrics that could be linked to outcomes, such as pathologic findings, with information that may need to be extracted from the electronic medical records.

As payment policy evolves, alternative payment models could be the future for radiologists. Alternative payment models focus on improving the health of a population and require physicians to take on financial risk. AI tools that can reduce costs and improve overall health of patients would be valuable to health systems or payers. These AI algorithms may take substantial time and investment to develop. Examples include tools that could predict future disease states on the basis of imaging examinations to allow for early intervention or the ability to assess the best therapeutic drug or intervention on the basis of specific imaging features of a cancer. These types of AI algorithms could theoretically decrease overall cost of care and improve patient outcomes,

and in this scenario physicians or health systems may be willing to pay for tools that improve population health in this way.

Conclusion

Payment for AI in the current fee-for-service environment may be challenging, and sustained adoption of AI may not occur within the framework of the IPPS and PFS. However, as payment systems evolve toward more mature value-based payment models where measuring improvement in quality becomes increasingly important at decreased costs, AI becomes a valuable tool for radiologists and health care systems. The entity that receives the most benefit likely will pay for AI and ultimately may consider this payment simply the cost of doing business.

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