Consumer Technology Association, producer of CES®

Issue Brief: Reimbursing Health AI and Innovative Technologies

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Existing reimbursement pathways for innovative healthcare technology tools are insufficient. As AI transforms the healthcare landscape at a rapid pace, more work is needed to find a sustainable financial model for buyers, sellers, and consumers.

The Health Division of the Consumer Technology Association (CTA®) supports the use of value-based healthcare technology that reduces costs and drives better health outcomes. It includes startups and global brands in the healthcare sector – including telehealth and personal health wearable companies, healthcare payers, health systems, and biopharmaceutical innovators – and provides policy advocacy, market research, and standards initiatives that advance the appropriate use of consumer technologies in the healthcare context.

I. Who Pays for AI?

As AI advances, so do healthcare technology tools that have the power to transform healthcare. Despite a plethora of new tools that have the potential to improve the efficiency and quality of the healthcare system, the question of who will pay for AI tools remains. Like many other parts of our healthcare system, reimbursement for AI is complex and uncertain. Hospitals and providers with limited IT budgets are hesitant to invest in expensive technologies without knowing if they will be reimbursed for using them, even if the technologies improve outcomes and reduce costs. Simultaneously, lacking a consistent reimbursement framework from the federal government to draw from, private payers are hesitant to fund AI-supported tools without clear criteria on safety, evidence-based efficacy, and long-term healthcare improvements.

Reimbursement policies in both the private and public sectors lag behind the fast-paced, ever-changing health AI landscape. This disconnect frequently leaves developers of health AI tools uncertain of whether their AI tool will be reimbursed or if reimbursement is sustainable over time.

II. There Are Limited Options for Federal Reimbursement

Health systems may seek reimbursement from the federal government for the use of AI in a healthcare setting, but the mechanisms to do so are relatively limited. Many times, payment is guaranteed for a brief period – usually three years – after which the AI may not be reimbursed at all or reimbursed at a lower price.

While there are limited options for federal reimbursement of AI use in a healthcare setting in the United States, causing hesitancy from developers and clinicians to fully embrace health AI, other countries have been successful in creating policies that encourage digital health/AI usage in healthcare. Germany's 2019's Digital Healthcare Act (DVG) stands out as a successful example. Within the provisions of DVG, the Digital Health Application program was created, which allows providers in Germany to prescribe digital healthcare applications with a low-risk class, intended to support patients with detection, treatment, alleviation, or compensation of injury and/or disability, can be provided to patients. Once a digital health application is in the official register, a standardized reimbursement price is determined with the manufacturer. Additionally, DVG has created national coverage rules and increased the use of value-based reimbursement.

The following is a deeper dive into the current status and challenges of the health AI reimbursement landscape:

CODING, COVERAGE, AND PAYMENT ARE NOT ALL-ENCOMPASSING: Providers participating in Medicare are reimbursed for work, direct practice expenses, and liability insurance as established through coverage and payment policies established by the Centers for Medicare and Medicaid Services (CMS). A national code set that represents healthcare services and procedures does not exist. CMS produces the Healthcare Common Procedure Coding System (HCPCS) and has adopted the American Medical Association's entire Current Procedural Terminology (CPT) code set as HCPCS Level 1 codes.

The CPT Editorial Panel is responsible for creating, modifying, and deleting CPT codes, whereas as HCPCS Level 2 codes are curated and administered by CMS. Coverage and payment policies are then established by CMS, who chooses which CPT or HCPCS codes to adopt and include in the annual Medicare Physician Fee Schedule payment regulation for the upcoming year.

CPT Category I codes are intended for established medical services, devices, disposable supplies, and procedures whereas CPT Category III codes are intended for emerging technologies and have an eventual sunset date. Category III codes do not require the same level of evidentiary basis as do Category I CPT codes and are not typically reimbursed by Medicare. Although some CPT codes may be general in nature, they are intended to provide specific descriptions and to not overlap with other codes.

In certain circumstances, the CPT Editorial Panel develops educational materials or appendices within the code set to better inform professional coders and providers about CPT content. Recently, the CPT Editorial Panel adopted Appendix S: AI taxonomy for medical services & procedures. Appendix S did not attempt to define "AI" but rather helped classify "the work done by machines" within the context of services and procedures as "assistive," "augmentative" or "autonomous." The Panel developed Appendix S given the increasing number of AI coding requests and applications it has received over the past few years. As the number of AI-powered medical devices and solutions increase, so will the need to better describe AI in medicine.

HOSPITALS HAVE TWO WAYS TO BE REIMBURSED: In Medicare, hospitals are reimbursed for services through two respective payment systems. Outpatient services are paid for through the Outpatient Prospective Payment System (OPPS) and inpatient services are paid for through the Inpatient Prospective Payment System (IPPS), and each has its own mechanisms for paying for emerging technologies.

Under OPPS, hospitals can receive pass-through payments for new devices, drugs, biologics, or radiopharmaceuticals or use the New Technology Ambulatory Payment Classification (APC) for AI algorithms that have been designated as software as a service. While some AI tools have been incorporated into the OPPS through this pathway, there are very few due to the limiting criteria for eligibility. The New Technology APC is time-limited, meaning after claims data is available, those items or services must be reclassified to other APCs and typically at lower payments to continue being part of the OPPS fee schedule.

Under IPPS, New Technology Add-on Payments (NTAP) are additional reimbursements that are added onto existing diagnosis-related group (DRG) payments – the primary way items and services are reimbursed through the IPPS. NTAP is a program that provides temporary, (up to three years) bundled payments that allow hospitals to pay for new technologies. This payment pathway has limitations, though, because the technology must meet specific criteria, such as needing to be "new and not substantially similar" to any others, be inadequately paid for under the current system, and demonstrate significant clinical outcome improvements to qualify. Very few algorithms have qualified for NTAP to date.

A PROPOSED COVERAGE PATHWAY FOR EMERGING TECHNOLOGIES: In 2023, CMS proposed the "Transitional Coverage for Emerging Technologies (TCET) pathway, which is intended to help certain devices designated through FDA's Breakthrough Devices Program to have a novel pathway towards Medicare coverage. The TCET pathway will be available for devices that meet certain required criteria (along with FDA Breakthrough Device designation) such as a determination that the product fits within a Medicare benefit category, that it is not already the subject of an existing Medicare National Coverage Determination (NCD), or otherwise not excluded from coverage through law or regulation. CMS anticipates accepting up to five TCET candidates per year, with a goal of finalizing an NCD within six-months after FDA market authorization for each. While this program may be promising for some emerging medical devices, it remains unavailable for Software as a Medical Device (SaMD) which does not qualify for TCET. Due to current regulations, SaMD is considered an indirect practice expenses and excluded from payment under existing benefit categories and contrary to the required criteria for TCET. Only Congress may establish new benefit categories which are created through statute.

PIECEMEAL AND INCONSISTENT COVERAGE LEAVES PROVIDERS IN A DILEMMA: Payment for digital health technology from the federal government is complex and not always sustainable, leaving providers and other stakeholders to question whether it is worth investing in these innovative but sometimes very expensive tools. Additionally, even with the advent of several new payment pathways, much of the current federal reimbursement landscape focuses heavily on health technology that qualifies as a medical device. There are plenty of health AI technologies that do not classify as a direct medical device, yet still can significantly improve patient care. The question of how the federal government may financially support providers who choose to deploy these services to improve their patients' care is yet to be answered, whether that be through the existing Medicare payment pathways or through a value-based, alternative payment model.

III. Private Health Plans Do Not Consistently Cover Health Tech

Without guidance or a clear framework from the federal government to draw from, private health plans are left to decide whether to pay for new digital health tools at their own discretion. Even when payers are inclined to include these tools, they face significant challenges in determining each tool's proper reimbursement rates, value propositions, and appropriate payment models.

Some payers bring certain digital health tools in-house, offering digital health products directly to their members. Ohers also reimburse providers for the use of different health technology tools, but this type of coverage varies widely across plans. Even for more established health technology services like remote patient monitoring and virtual consults, commercial payers have little alignment among themselves or with Medicare in coverage policies. While there is currently limited information about private payers' coverage policies of health AI technologies, one can imagine that it is even more disparate and inconsistent than that for services like remote patient monitoring. This inconsistency may have negative impacts on providers' willingness to adopt new technologies.

IV. Proving and Recognizing the Value of Health AI Tools

The health technology sector is quickly evolving, with new digital health tools being introduced every day. As policymakers and private healthcare organizations attempt to chart the future of digital health payment, several action items may help this process:

UNDERSTANDING CURRENT PRACTICES: We need a better understanding of how private payers are currently paying for health AI. Getting a full picture of the payment landscape will help digital health companies better position their business models and will help educate policymakers who are currently thinking about how to establish future payment pathways for innovative technologies in healthcare.

ESTABLISHING VALUE: Before investing, both payers and providers want a digital health tool to demonstrate its effectiveness and provide evidence that they can expect a return on their investment. A framework that establishes clear criteria to assess the value of AI tools will help healthcare organizations make decisions investing in, reimbursing for, and scaling certain technologies. Independent groups like the Peterson Health Technology Institute are beginning this work, which will hopefully end by creating baseline criteria for digital health companies to incorporate into products and accelerate adoption.

Ultimately, the potential for AI tools to improve patient outcomes and reduce costs will only be realized if these tools are covered and reimbursed based on value, and not as another item paid within the fee-for-service model.