

New Technology Add-On Payment (NTAP) for Viz LVO: a win for stroke care

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INTRODUCTION

The Centers for Medicare and Medicaid Services (CMS) recently granted a New Technology Add-on Payment (NTAP) for Viz ContaCT (Viz LVO) by Viz.ai, Inc, an applied artificial intelligence healthcare company.¹ This is the first time CMS has reimbursed an artificial intelligence (AI)-based software using this designation. It applies to Viz.ai's acute ischemic stroke product, Viz LVO, officially known as Viz ContaCT, under which the ICD-10 Procedure Coding System (ICD-10-PCS) procedure code 4A03×5D was established. Viz ContaCT is an AI-based system that creates a parallel alert system whenever it detects a large vessel occlusion (LVO) on a computed tomography angiogram. The images are viewable on a mobile application which combines HIPAA (Health Insurance Portability and Accountability Act)-compliant group messaging functionality with a mobile PACS Viewer. Users can view the images, make triage decisions, and communicate with other members of the care team through chat functionality.

Beyond the specific designation, this decision may have far-reaching implications for stroke care and for reimbursement of AI-enabled applications.

What is NTAP?

At a national level, reimbursement is how health care incentivizes helping patients. Medicare pays for a patient's hospital stay according to the Inpatient Prospective Payment System (IPPS) under a single bundled payment, which includes all costs. These payments are captured under the Medicare Severity Diagnosis-Related Group (MS-DRG) system. While the MS-DRG rates are updated annually, the payments are based on Medicare claims data accrued over a 2 to 3 year period. The result is that payments lag behind true costs, particularly for care using new and expensive technologies.²

Introduced in 2001, the CMS NTAP program was created by Congress to help close this gap and support timely access

to innovative therapies for the Medicare population. For technologies accepted under this program, CMS provides an additional payment to hospitals above the standard MS-DRG payment amount. There is an application, review, and approval process for the NTAP program.

There are three criteria for NTAP:

- ▶ Newness—the technology must be novel, that is, <3 years old. Typically this excludes Food and Drug Administration (FDA) 510k clearances, as by definition, these are predicated on another technology
- ▶ Cost—the technology is not adequately covered under the existing MS-DRG
- ▶ Substantial clinical improvement—the technology must prove to CMS that it provides a substantial clinical advantage over other available technologies, typically in the form of improved patient outcomes.

NTAPs are granted based on evidence submitted with respect to specific products. Other AI companies can submit an application to CMS demonstrating they also meet the above criteria, for consideration in a future IPPS NTAP.³

How the Viz.ai NTAP works

In 2019, CMS revised its rules around reimbursement using the NTAP program, agreeing with concerns that capping the payment at the 50% rate may not adequately support healthcare innovations. In response, 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.⁴ For the Viz.ai NTAP code, the additional payment is capped at \$1040.

To qualify, a patient must be a Medicare patient with a suspected stroke, and the estimated cost must exceed the Medicare reimbursement. As the name suggests, the payment is added on to the DRG payment to the hospital for a qualifying patient, so only applies if the patient is admitted. In my institution, Medicare patients account for approximately 51% of our code strokes, and nationwide approximately 45% of these patients have an estimated cost greater than the DRG payment.⁵ For these

patients, when the hospital uses Viz LVO the NTAP will help to defray costs with an additional payment, up to \$1040.

Why this is a big deal for stroke

Given the current revenue climate, a \$1040 reimbursement per patient may seem high. In approving NTAP for Viz LVO, CMS recognized the clinical benefit of Viz LVO in the management of patients admitted with stroke. Thrombectomy has been proven to be a highly effective treatment for acute ischemic stroke, and we know that patients do significantly better the sooner they are treated.⁶ It has been estimated that in each minute of an ongoing stroke, 1.9 million neurons, 14 billion synapses, and 12 km (7.5 miles) of myelinated fibers are destroyed and that the ischemic brain loses neurons at an hourly rate equivalent to 3.6 years of normal aging.^{7,8} Data from the Highly Effective Reperfusion Evaluated in Multiple Endovascular Stroke Trials (HERMES) collaborative suggests that every minute delay results in a loss of 4 days of disability-free life.⁹ Clearly, delays in stroke care result in significant negative outcomes both for patients and for the financial well-being of the healthcare system.

Cost-benefit analysis of thrombectomy yields similarly striking results: achieving expanded treatment in cerebral ischemia 3 (eTICI 3) over eTICI 2b reperfusion resulted on average in 1.31 incremental quality-adjusted life-years (QALYs) as well as healthcare and societal cost savings of \$10327 and \$20224 per patient, respectively. An estimated \$21 million and \$36.8 million for the US healthcare system and society, respectively, could be saved by a 10% increase in the eTICI 2/3 reperfusion rate of all endovascular thrombectomy-treated patients with stroke.¹⁰

The median loss in net monetary benefit of thrombectomy per minute was calculated to be \$1059, and saving 10 min on average across the USA would save \$249 million annually.⁹ Implementation of Viz LVO has been demonstrated to save 66 min on average,¹¹ suggesting a significant return on investment for CMS.

The intent of the NTAP program is to encourage early adoption of new and clinically effective technology. The reimbursement, however, may also help to avoid perverse incentives in the healthcare system, in which clinically appropriate transfers to comprehensive stroke centers may be discouraged by either the receiving or sending facilities, due to issues of avoiding the cost of sicker patients or

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retaining the reimbursement of funded patients.¹²

We have made great progress in our ability to treat stroke and change lives. Evidence of health benefits, however, do not necessarily translate into evidence of financial feasibility, and healthcare systems may defer purchase of potentially life-saving and cost-saving products until the financial concerns have been alleviated. This decision represents a move by CMS to remove some of those barriers.

Why this is a big deal for health care

CMS has previously proposed reimbursement for use of AI-enabled technology—specifically automated retinal imaging—in its 2021 Medicare physician fee schedule proposed rule.¹³ This reimbursement model addresses diagnostic applications that perform functions analogous to those otherwise performed by physicians, but it is insufficient for novel uses, such as parallel processing and triage.

CMS grappled with several of these new concepts in its process of approving Viz ContaCT for NTAP.¹ It had to determine how to define cost for an application with a subscription model—a common payment model for software, but not for physical tools. It had to understand how it should consider the “novelty” of technology given AI’s capacity for learning and improvement. It also had to consider the value of technology to improve workflow, going beyond the traditional paradigms of straightforward diagnosis and treatment. Although healthcare AI tools and companies have been in the headlines over the past few years, healthcare has been slower to adopt AI-powered applications than other industries. Initial excitement over proofs-of-concept and early progress can quickly die without a viable financial model to support further development and deployment.

NTAP itself is unlikely to represent a comprehensive solution for large-scale AI market success, given the inherent limitations. It is a time-limited decision which is reviewed annually and expires after 3 years, at which point the cost of the technology may or may not be incorporated into the Medicare reimbursement calculation, and the cost-benefit considerations will change. The NTAP decision specifies a single product as qualifying for the additional payment, and CMS has to determine whether this applies to other products or not; to date, no other products have been deemed eligible by CMS. Additionally, the NTAP requirement of demonstrating novelty, high cost, and improved clinical outcome represents

a barrier to acquire or even to attempt to acquire such a designation.

That said, the fact that CMS has begun to answer some of the questions of how AI-powered tools can be incorporated into reimbursement structures has illuminated a possible pathway to a realistic healthcare market for this technology.

CONCLUSION/TAKEAWAYS

In health care, doing the right thing for patients unfortunately is not enough. In order for new techniques, tools, and technology to be accepted and spread, they have to be incentivized. This is a landmark decision, as it marks the beginning of figuring out how we incentivize tools that target what is often the most challenging part of health care—the workflow issues that result from fragmented and unoptimized systems. It’s a start to understanding how we might pay for advanced technology like AI, so we can accelerate adopting increasingly effective tools into our practices. More specifically, it’s a win for stroke care, and the patients who will benefit from the treatment that we can provide, now more efficiently.

Time will tell, but we may look back and decide that this was the inflection point, the beginning of a new age in acceptance of this technology into the healthcare mainstream.

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