

## GUEST ARTICLE

# NOVEL TECHNOLOGIES REQUIRE A CRITICAL PATH TO CMS REIMBURSEMENT



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“There is an urgent need for a clearly defined set of procedures and policies at CMS that would result in rapid reimbursement decision making for novel, high-value technologies.”

**M**ost well-known stories about historic medical breakthroughs tend to focus on those strokes of luck and fateful coincidences that come at key points on the pathway to innovation: a Petri dish full of staphylococci bacteria that Alexander Fleming just couldn't keep clean (penicillin), or the pair of frog legs that kept kicking while clipped to a metal wire (neurophysiology)<sup>1</sup>.

In these tales, once luck removes the obstacles, inspiration follows quickly and the happy ending is a *fait de compli*. Often, the long and methodical road from luck and inspiration to practical application barely rates an afterthought.

Unfortunately, stories of the opposite variety—about innovations that get bogged down on the road to easing suffering and saving lives—have grown increasingly common among product developers in their dealings with the Centers for Medicare and Medicaid Services (CMS). What they reveal is the urgent need for a clearly defined set of procedures and policies—a “reimbursement critical path”—at CMS that would result in rapid reimbursement decision making for novel, high-value technologies. Detours on the road to innovation In the updated version of our innovation story, detours and dead ends triggered by a lack of efficiency, transparency and predictability in the reimbursement process riddle the road from breakthrough to follow through. Consider these real-life examples culled from our membership:

- Company A has developed a unique method for wound debridement, but has been unsuccessful in reconciling differing advice between Medicare contractors and CMS central office staff on appropriate coding for the therapy.

- Company B's product can be used to treat patients following certain kinds of strokes, but a conclusion on whether or not the product fits within a Medicare benefit cate-

gory has remained unresolved after more than a year.

- Company C has developed a procedure for treatment of chronic reflux esophagitis. Unfortunately, issues pertaining to coding and payment rates persisted so long that the company was forced to shut down before the issues could be resolved.

It's worth noting that the roadblocks described above have nothing to do with the efficacy of these products or procedures. They have already proven to the Food & Drug Administration (FDA) that they can provide improved outcomes for Medicare and Medicaid beneficiaries. The snafus in question are purely administrative in nature.

The irony here is that new treatments often possess the most promise for delivering significant clinical benefits (i.e., they have the highest potential value), yet the more novel a technology is, the more likely it will be to raise significant coverage, coding or payment hurdles—as no existing mechanism for decision making can provide a clear guide. What we need is a mechanism for recognizing such innovations early on and fast-tracking them (as opposed to letting them—and their developers—languish), so that all stakeholders can realize their benefits in the most timely manner possible.

NVCA's reimbursement critical path In response to this pressing need, the NVCA has issued a set of recommendations that, taken together, outline a critical path to CMS reimbursement decision making. This path has been designed to significantly improve efficiency and transparency, improve process predictability (thus enabling developers and investors to better manage resources and risk) and spur increased investment in novel, high-value technologies.

**1. Expand the role of the Council on Technology and Innovation (CTI).** As a cross-component entity, the CTI is ideally positioned

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to support the reimbursement process, which often requires coordination across several CMS components, and in some cases coordination with other government agencies. The CTI could expand its role by holding meetings with stakeholders to collect input regarding helpful critical path components, by developing a written prioritized plan for instituting suggested reforms and presenting the plan to the CMS administration, and by designating an ombudsman for product developers who are having difficulty resolving specific reimbursement problems despite reasonable diligence in working through existing decision making mechanisms within CMS.

**2. Develop process descriptions.** Many basic questions and problems could be resolved with modest efforts by CMS to make its various reimbursement policy making pathways, and their interconnections, more transparent. As a first step, CMS should issue a roadmap (something that we understand is under development) that describes the primary coverage, coding and payment processes at Medicare for investors and life sciences companies.

**3. Establish explicit time frames.** CMS should commit to reasonable decision-making time frames for all reimbursement policy processes. This will help product developers manage resources and risk as well as cut down on the amount of time that young companies must subsist on their venture capital (i.e., reduce their burn rate). Again, a town hall meeting of stakeholders may help identify priority processes for time-frame development.

**4. Provide reimbursement for devices granted expedited review by the FDA.** CMS and the FDA have worked together well in the past (e.g., coronary stents and ventricular assist devices) and need to follow those examples moving forward. As a start, we propose that medical devices that are undergoing expedited review by the FDA should be simultaneously reviewed by CMS to ensure that potential coverage, coding and payment policy issues have been identified

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well before final FDA approval. Once the mechanism for expedited reimbursement review has been established for medical devices undergoing expedited FDA review, CMS could expand this approach to other technologies determined to meet the criteria established for novel and high value technologies.

**5. Clarify evidence requirements.** CMS should accelerate its work on developing guidance documents that clarify the scientific evidence requirements for coverage decisions (both national and local), as well as coding and payment decisions. Efficiency and transparency would also be improved by meeting directly with early stage companies to provide feedback on expectations for the design of clinical trials that will satisfy coverage requirements for the technologies they are developing.

**6. Clarify standards for new technology add-on payments.** The application and review process for new technology add-on payments, particularly the administration of the substantial clinical improvement requirement, is inconsistent and opaque. To clarify it, CMS should convene a panel of researchers, clinicians, industry representatives and patient

groups to develop specific, generally applicable criteria for the determination of whether a new product represents a substantial clinical improvement, including the creation of objective standards for the use of external data.

**7. Explore options for improving coding processes.** Coding problems are a major source of uncertainty and frustration for product developers, and the degree of friction in resolving these problems is often inconsistent with the potential health benefits of a product. There is likely no easy fix here, as the coding process involves a number of complex concerns and input from numerous specialty societies. However, many processes remain opaquely defined, which undermines the interests of all stakeholders. Therefore, a forum focused on discussing current problems and potential solutions may be the best first step.

At this point, those in CMS may be saying, “Great ideas, but with what resources?” It’s a fair question—and not an easy one. In the same way that the FDA depended on revenue from user fees to generate improvements, CMS may need to explore creative mechanisms to support these proposed changes. In this spirit, we again volunteer to play a role in developing such solutions.

The road to reform, very much like the road to innovation, can be long and fraught with uncertainty and unpredictability. But it remains the only pathway available to us for improving outcomes for all CMS stakeholders.

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*1: Discovery, Chance and the Scientific Method. Access Excellence Classic Collection. By: Fran Slowiczek, Ed.D.1 and Pamela M. Peters, Ph.D.*