



A Proposal for a Reimbursement “Critical Path” for CMS

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Background and Purpose

The National Venture Capital Association (NVCA) is the trade association that represents the U.S. venture capital industry. NVCA’s mission is to foster greater understanding of the importance of venture capital to the U.S. economy and to support entrepreneurial activity and innovation. Because the venture capital community works closely with the companies developing innovative new technologies, the NVCA offers a unique perspective on Medicare’s procedures and policies for coverage and payment of emerging medical products.

NVCA believes that the interests of Medicare beneficiaries, CMS, product developers and investors could all be served by improving the efficiency, transparency and predictability of the reimbursement process, particularly for novel, high value technologies. CMS has already taken several important broad steps in this direction, including refinements in the national coverage process and establishment of the Council on Technology and Innovation. We believe that building on these initial efforts will help to ensure a favorable economic and policy environment for making valuable new technologies available to patients and clinicians.

Through discussions with venture capital investors, early stage life sciences companies, reimbursement consultants and policy experts, we have identified a number of circumstances under which reimbursement decision making is impeded due to problems with the reimbursement process itself, and not primarily because of inherent questions about the clinical effectiveness or value of the technology under review. We believe that it is in the interest of all stakeholders to minimize such barriers. Such problems are particularly likely when a technology is novel and may therefore not fit readily into established pathways for coverage, coding and payment. Yet it is precisely these novel technologies that are most likely to represent important clinical breakthroughs, and to significantly improve outcomes for Medicare beneficiaries.

The goal of the NVCA Workgroup on Healthcare Innovation Policy (WHIP) is to identify potential improvements in reimbursement procedures and policy that will help ensure access to important, clinically effective, high value technologies. In this memo, we introduce the concept of a “Reimbursement Critical Path”, having chosen this name to highlight the common goals shared by this effort and the FDA Critical Path initiative. Both policy initiatives seek to support efficient development and adoption of novel, clinically effective and high value technologies.

Specific objectives

The reimbursement critical path would be a clearly defined set of procedures and policies that would result in rapid reimbursement decision making for novel, high value technologies. This pathway would include refinements in coverage, coding, and payment. Because most novel technologies will be different than existing technologies, existing reimbursement mechanisms may create uncertainties and delays that impede the development of optimal reimbursement requirements for that technology. The recommendations discussed below are intended to ensure that potential reimbursement barriers to novel technology are identified and refined.

The proposed policy refinements may have a profound impact on investment in and appropriate use of novel, high value technologies. We are particularly attentive to the risks associated with investment in those promising technologies for which there is not yet a well-established reimbursement pathway. The reimbursement critical path could help ensure that such technologies became more attractive for financial support.

It is also important to ensure that reimbursement issues are fully considered in the context of ongoing FDA critical path discussions, in which NVCA is also engaged.

What are novel, high value technologies?

We propose to focus initial attention on improving reimbursement mechanisms for technologies that fit an explicit definition of “novel and high value”. We believe that efforts to streamline reimbursement for this subset of technologies may lead to policy enhancements that would impact a wider range of technologies in the future, improving the predictability and transparency of these processes, while ensuring the reimbursement policy works more effectively to enhance both innovation and value in health care.

While it will probably be necessary to go through a process to develop criteria to identify those technologies that are novel and high value from the perspective of CMS, it should be possible to begin pilot efforts at rapid reimbursement decision making by focusing on technologies deemed by the FDA to be eligible for accelerated approval (drugs/biologics) or expedited review (devices). The FDA has existing mechanisms for designating specific technologies to be of sufficient potential public health and clinical importance to qualify for special attention during regulatory review. It may be reasonable to assume that all or most of these technologies would merit preferred reimbursement attention as well.

For a CMS-specific definition, we have done some preliminary thinking about how to define novel, high value technologies: A novel technology is a product that represents the first expression of a technology or use of a technology, that is likely to have clinically significant benefit, and raises potentially significant coverage, coding, and/or payment hurdles.

A number of considerations would be factored into the judgment about whether a technology is “potentially of high value”, from the perspective of the payer, the health care system, and society. The criteria listed below will require further refinement, but are intended to capture some of the critical characteristics of new technologies that would reflect on their value.

- *Safety*: The degree to which the technology may reduce the risk of adverse events for patients or health care providers.
- *Clinical effectiveness*: the expected magnitude of improvement in patient health outcomes, including mortality, morbidity, quality of life, functional status. Improvements in the timely and efficient delivery of care would also be a factor.
- *Clinical efficiency*: the expected impact of the technology on resource utilization, assessed at the level of individual patients. Short term and long term savings would need to be considered, as well as savings that occur across the various care settings.
- *Strength and consistency of evidence*: the level of confidence that the judgments about clinical effectiveness and clinical efficiency are reliable based on scientific studies, pathophysiologic reasoning, economic modeling, clinical judgment and other sources of information. The assessment of the evidence will need to be undertaken with recognition of the practical and economic challenges to being able to definitively prove benefits for novel technologies.
- *Organizational efficiency*: the expected impact of the technology on resource utilization, assessed at the level of health care institutions and the health care system. This would include impacts on worker productivity, increasing the capacity to use existing facilities and technologies, etc.
- *Support future innovation*: Consideration should also be given to those technologies that may represent an early generation of a new category of technologies for which refinements will provide major benefits, and may also lead to important related applications.

Examples of novel, high value technologies

| Currently marketed | Under development |
|--|---|
| Angioplasty Coronary stents Drug eluting coronary stents Kyphoplasty Laproscopic gallbladder surgery Implantable defibrillators Catheter arrhythmia ablation RF/microwave BPH Percutaneous femoral closure Carotid stents Spinal fusion cage | Biodegradable or novel stents Neurostimulation PFO closure Vulnerable plaque Cartilage repair Endoscopic lung volume reduction Cardiac remodeling device Ultrasound enhanced perfusion Hypothermia Percutaneous DVT treatment Spinal Nucleus Replacements Dynamic Spine Replacements |

Specific Recommendations

The recommendations provided below are those that we believe are sufficiently focused and concrete that they can be implemented within a reasonable amount of time and with existing CMS staff. A few of the recommendations will require more time, further thought and discussion, and additional resources. Whenever possible, we include a specific example to illustrate the type of problem that each recommendation is intended to address, though in many cases we have not provided the name of the company involved at their request. Addressing the concerns that have lead most companies to requesting anonymity in this exercise is a symptom that we hope will be improved through continued dialogue on reimbursement issues.

Recommendation #1: Expand the role of the Council on Technology and Innovation

The Council on Technology and Innovation (CTI) could function as the primary organizational component to support development and implementation of the reimbursement critical path. Because efficient reimbursement policy requires coordination across several CMS components, and in some cases coordination with FDA, NIH, AHRQ and other institutions, a cross-component entity like CTI is ideally positioned to support this process.

The existing statutory language establishing CTI is also entirely consistent with the objectives of the reimbursement critical path, as that language directs the CTI to focus on improving coordination for coverage, coding and payment in order to minimize barriers to access to new technologies.

Rec 1(a): The CTI could be asked to develop a written strategy to be presented to the CMS administrator with a prioritized plan for administrative and regulatory reforms that might support continued progress toward the goal of efficient reimbursement procedures for novel, high value technology.

Rec 1(b): It would be useful to have one or more public meetings at which stakeholders could present ideas for possible inclusion in the CTI strategic plan.

Rec 1(c): The executive director of the CTI, or a designee of that individual, should serve as an ombudsman for product developers who are having difficulty in resolving specific reimbursement problems despite reasonable diligence in working through existing decision making mechanisms within CMS. This is not intended to be a function through which product developers would appeal decisions that they find undesirable, but rather is for those situations in which the usual procedures have not generated a clear policy conclusion after a reasonable period of time and effort.

Recommendation #2: Develop process descriptions

A common problem for early stage companies is the difficulty of understanding which part of CMS handles which issues, and who they should be talking to about specific reimbursement problems. Many early stage life sciences companies and investors have hired reimbursements consultants because they are unable to identify the appropriate point of access to CMS policy processes and staff. Many basic questions and problems could be resolved with modest efforts by CMS to make their various reimbursement policy making pathways, and their interconnections, more transparent.

Rec. 2(a): CMS should develop a roadmap that describes the primary coverage, coding and payment processes at Medicare for investors and life sciences companies. This document would not need to be highly detailed, but should identify the major decision making functions, what part of the Agency has responsibility for that function, contact information of We are aware that such a document is currently under development, and look forward to seeing the first draft.

Recommendation #3: Establish explicit timeframes

For most early stage companies, particularly those developing medical devices and diagnostics, each month of delay in resolving a reimbursement issue can translate into a substantial “burn rate” for their investment capital. In some cases, a substantial delay in the time required to arrive at a definitive answer on a reimbursement policy question can lead to economic failure even for companies with potentially useful technologies.

Examples include:

- 1) a company that 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.
- 2) a company with a product used to treat patients following certain kinds of strokes, where a conclusion on whether or not the product fits within a Medicare benefit category has remained unresolved after more than a year.
- 3) a company with a procedure for treatment of a chronic reflux esophagitis that encountered multiple issues around coding and payment rates that were resolved too late to prevent the company from shutting down.

Clearly, Medicare is under no obligation to ensure the economic success of products without clinical value, but the Agency should make itself more accountable for completing their decision making processes in a timely and predictable manner – whether or not those policy processes are governed by fixed statutory timeframes.

Rec. 3(a) CMS should review current reimbursement policy processes that are not subject to fixed time frame and commit to a reasonable time frame within which these decisions will be made. For most such decision, a turnaround time of 3 to 6 months would seem adequate, though the Agency would be in the best position to determine what time frame would be reasonable. As noted further below, the Council on Technology and Innovation may be well positioned to oversee the development, implementation and monitoring for the proposed procedural improvements.

Rec. 3(b) In order to help identify and prioritize policy processes in need of improvement, CMS could hold a town hall meeting inviting stakeholders to present examples of problems encountered in resolving reimbursement issues. This would serve as an opportunity for CMS to gain a deeper understanding of the nature of these problems, and use that information to target their efforts to those processes that have proven consistently problematic.

Recommendation #4: Reimbursement for devices granted expedited review by the FDA

The potential value of greater coordination between FDA and CMS around review of novel technologies has been discussed over the past 5 years, and was mentioned as a priority in the report of Secretary Thompson's Medical Technology Innovation Task Force. FDA and CMS have some ongoing collaboration (e.g. biomarkers in oncology) and there are several examples of productive communication between CMS and FDA staff around the review of specific technologies (e.g. left ventricular assist devices, coronary stents).

We recognize that limitations on time constrain the level of collaboration than can be sustained between CMS and FDA, and would therefore proposed further exploration of carefully selected opportunities to increase coordination.

Rec 4(a): To begin with, we propose that class III 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 well before final FDA approval. This would give the product developer and CMS adequate time to address these issues, with the goal that any problems have been resolved by the time the product is approved for marketing by the FDA, leading to simultaneous regulatory and reimbursement policy implementation.

As an initial pilot test, several medical devices currently undergoing review by the FDA under expedited review could be handled through this process. This could almost certainly be done under existing authorities, would require limited staff time and resources, and should quickly reveal whether the approach offers a useful pathway for efficient reimbursement of novel, high value technologies.

The CTI might be well positioned to oversee the implementation and refinement of this expedited reimbursement process, ensuring that all necessary policy making functions within CMS completed their decision making in a timely fashion.

Rec 4(b): Once the mechanism for expedited reimbursement review had 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. A set of criteria have been proposed above, and these could serve as a starting point for further discussions within CMS, and between CMS and other stakeholders.

Recommendation #5: Clarify evidence requirements

The CMS has begun a process of becoming more explicit about the evidence requirement needed for national coverage decisions. The Agency has indicated its intention to generate guidance documents for coverage decision making regarding important categories of technologies, to continue its efforts to more clearly define the type of scientific evidence necessary to obtain national coverage under Medicare. None of these guidance documents have yet been issued, and we recognize that there are staffing limitations that contribute to the slow progress in this area.

More recently, it has become apparent that CMS is using evidence of comparative effectiveness in decisions about coding (whether or not to assign two similar devices to the same HCPCS codes) and payment (use of least costly alternative payment rates for drugs with similar therapeutic effects). As life sciences companies plan their clinical research programs, it is important that the scientific standards to be used in these decision making processes be explained in as much detail as possible.

Rec 5(a): 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. It would be particularly valuable to provide more detailed guidance regarding the circumstances under which CMS assessment of the benefits and risks of new technologies may differ from the determinations made by the FDA.

Given staff limitations, we would encourage CMS to explore the possibility of obtaining outside technical assistance in developing draft guidance documents, possibly from the academic community and/or from industry.

Rec. 5(b): We would also encourage the Agency to expand its efforts to meet with early stage companies to provide feedback on the Agency's expectations for the design of clinical trials that will satisfy coverage requirements for the technologies they are developing.

Recommendation #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. From FY 2003 through 2006, CMS approved six of eleven unique applications where the agency had to apply judgment about whether the applicant had satisfied the criteria. This figure masks the considerable extent to which the unpredictability of the process has likely deterred many more would-be applicants.

At present, in order to qualify for an add-on payment, an applicant must demonstrate, in addition to the newness and cost requirements, that the product in question “represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.” CMS has suggested that applicants can satisfy this requirement by showing, for example, that their product “reduces mortality, decreases the number of hospitalizations of physician visits or reduces recovery time.” However, CMS has not provided clear guidance with respect to the type of data that applicants must submit to make such a showing, and review of the past applications of this general evidentiary standard by CMS are not consistent enough to provide useful guidance to product developers who may be interested in designing studies to demonstrate that their products do provide a “substantial clinical improvement”. Are randomized head-to-head trials against current standard of care required in every case? Review of past decisions indicates that this is sometimes, but not always necessary, and in other cases not by itself sufficient. We would also suggest that technologies that improve outcomes by significantly reducing disability, improving quality of life and improving functional status should be considered to meet the substantial clinical improvement requirement.

Rec 6(a): The NVCA proposes that CMS convene a panel of stakeholders, including 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.

Recommendation #7: Explore options to improve coding processes

At a recent meeting of a half-dozen experienced reimbursement consultants, one of the most commonly cited reimbursement challenges related to obtaining appropriate billing codes in a timely manner. Generally speaking, the problems encountered with HCPCS codes involved difficulties in obtaining unique codes that reflected meaningful differences between a new technology and existing products assigned to the same code.

Problems encountered with CPT codes often related to the poorly-defined process of convincing the relevant specialty societies to support a level one code for a specific new technology. Many examples were offered of inconsistencies in the evidentiary and utilization requirements of different specialty societies for obtaining CPT level I codes, and the significant impact that individual clinical champions or opponents can have in the CPT process.

Problems were also cited in the process of assigning category III codes versus unlisted codes, and the difficulty of obtaining the clinical use necessary to qualify for a category I code when payers will generally deny payment when a category III code is assigned.

In each instance assigned above, the success of the technology in the reimbursement process is influenced by factors unrelated to its clinical value, and is subject to uncertainties that produce no benefit to payers, clinicians, patients or product developers.

Examples included:

- A modified urinary catheter for which there was reasonably good evidence that complications with infection and strictures were reduced
- A device used in surgical therapy for chronic gastro-esophageal reflux for which it was not possible to obtain CPT level 1 code in a reasonable time frame
- A device approved as a non-surgical alternative to tubal ligation, which only succeeded in obtaining a CPT level 1 code through aggressive intervention by a single passionate and persuasive clinician

Rec 7(a): Within the scope of this initial assessment, we were able to determine that coding problems are a major source of uncertainty and frustration for product developers, and that the degree of friction in resolving these problems was often inconsistent with the potential health benefits of a product. We were not, however, able to identify specific, concrete actions that CMS might take to improve the HCPCS and CPT coding process. We would therefore recommend that a town hall meeting be convened to solicit more detailed testimony on the nature of these problems, and to collect potential solutions. NVCA will be doing additional work in this area that we would plan to present either privately to CMS staff or at a public event.

Recommendation 8: Determine additional resource needs

It is clear that implementation of the procedural and policy improvements described above will require additional staff and administrative resources. Much as FDA improvements were dependent on revenue from user fees, CMS may need to explore creative mechanisms to support these proposed changes. The NVCA would be happy to work with CMS to explore acceptable mechanisms through which adequate resources could be obtained.