

Planning for Successful Medical Device Reimbursement:

NAMSA®

So Your Device Is Cleared, Now What?

By Tiffini Diage, MPH

Health Economics



Key Considerations for Targeting Success of Medical Device Sales



Planning for Successful Medical Device Reimbursement: So Your Device is Cleared, Now What?



Tiffini Diage, MPH (tdiage@namsa.com) is a Medical Research Manager with NAMSA, and has formerly held senior level clinical and regulatory positions within medical device organizations. She holds a Masters in Public Health from University of Wisconsin Madison and has a professional certification in Consumer Health Advocacy. Ms. Diage specialized in health outcomes and economics research consulting helping companies develop clinical trials, publications, and reimbursement strategies for US and international adoption of new technologies.

Congratulations, you've received approval to market your device in the United States and possibly international regions as well. Given the time and effort it takes to get approval from a regulatory body such as the US FDA, this is quite an accomplishment. Yet clearance alone does not guarantee a revenue stream. Acceptance within the medical community, strong sales, and market growth are what determine the next stage of product success. Reimbursement and payment are key factors in determining sales growth and market adoption. Even if sales are forthcoming, additional reporting and compliance requirements may threaten to hinder momentum. Proper planning is necessary to ensure you hit the ground running the second you receive that long-awaited clearance so you can begin generating revenue as soon as possible after what can be a long regulatory approval process.

Medical communications, reimbursement, and continued compliance with regulatory requirements are integral to the successful sale and distribution of medical devices. Each of these elements requires continued clinical and economic data collection, such as observational studies and cost benefit/use analyses, as well as dissemination of the information collected. Early planning for each area is essential. Acceptance by the medical community is based on compelling and readily available outcomes data. Well-designed outcomes testing, KOL

Planning for Successful Medical Device Reimbursement: So Your Device is Cleared, Now What?

Proper planning is necessary to ensure you hit the ground running the second you receive that long-awaited clearance.

advocacy development, abstract presentation at society meetings, and peer-reviewed journal articles are important tools for gathering and disseminating clinical data for your product. These activities require both close relationships with physicians and strategic planning.

Reimbursement: Coverage, Coding, and Payment

Reimbursement is often one of the first elements a company will consider when developing a product. Companies may assume medical need will ensure reimbursement. However, in the age of the Affordable Care Act, the need to reduce health care expenditures while simultaneously improving health outcomes means medical need is no longer sufficient. A reimbursement strategy is often the first step that companies formulate in determining how to successfully market their product and analysis of the current reimbursement landscape is imperative. In the current regulatory and reimbursement climate reimbursement studies alone fall short of what is needed to bring in actual sales. Companies need to develop a strategy for how their product will be paid for, which may not always be through reimbursement.

Coverage, coding, and payment are the three pillars of reimbursement, and each stands alone. Coverage via a National Coverage Decision (NCD) or a Local Coverage Decision will only apply to new medical procedures and technologies that are not currently defined in the regulations. An NCD applies only to a fraction of new devices and requires a significant amount of clinical data. At least one publication of Class 1 data (ie, a randomized controlled trial, or RCT) is required. An additional challenge is the different emphasis placed on the approval process by the FDA and what is required for reimbursement by insurance companies that typically follow the Centers for Medicare & Medicaid Services (CMS) guidelines. The FDA stresses safety and efficacy while the CMS focuses on superiority of a product relative to the gold standard. This difference makes it challenging for a company to achieve both clearance and coverage, with the FDA making decisions on a predicate device and CMS looking for novelty. While the parallel path initiative is being pursued (companies meet with FDA and CMS to determine clinical requirements for approval and reimbursement simultaneously), no data exist on the program's success.

Coding is the language of CMS, private payers, facilities, and

Planning for Successful Medical Device Reimbursement: So Your Device is Cleared, Now What?

Coverage, coding, and payment are the three pillars of reimbursement, and each stands alone

physicians. Coding translates into payment. Without a proper code, procedures and products are not paid for. There are numerous types of codes, depending on where a procedure is performed (inpatient, outpatient, skilled nursing facility), who is performing the procedure (physician, nurse, technician), and what equipment is involved (durable equipment, consumable, new technology). Coding is where the majority of companies focus reimbursement analysis for cleared products. Determining how and where your product fits into the coding landscape can be a complicated and sensitive matter requiring thorough analysis. Creating a new code or obtaining an add-on code for additional payment to an existing procedure is an avenue many companies pursue. This strategy can be very successful, but requires a good body of clinical data—usually Class 1 and Class 2 data presented in peer-reviewed journal publications. Notably, a new code does not always result in payment; there are numerous codes that have a value of zero.

Payment is the coup de grace of all the hard work and effort that it took to get a product cleared for commercial sale. After coverage determination and coding hurdles have been crossed, the amount a hospital or physician practice will get paid for your product determines sales. However, successful sales strategies can come not only from reimbursement, but also from a well-defined value proposition. Many medical devices are used as part of inpatient or outpatient procedures that are covered by a single payment to the hospital for the procedure (via DRG or APC code, respectively). Hospital systems are incentivized to lower cost and improve quality. Companies can often create a value proposition for direct purchase of devices that reduce length of stay, readmission, and/or procedure time. Physician advocacy and clinical data are usually required in order to create this value proposition for the hospital.

Outcomes Data: RCTs AND Postapproval

The need for clinical data is a common theme in obtaining reimbursement and generating sales of a medical device. Both Class 1 data (RCTs) and Class 2 data (prospective registries, longitudinal studies, case control studies) are necessary. Whether you're petitioning to CMS, a private insurance company, a hospital, or a physician, "real world" Class 2 data is becoming more valuable. While RCTs can provide the scientific validity of device safety and efficacy, the rigorous

Planning for Successful Medical Device Reimbursement: So Your Device is Cleared, Now What?

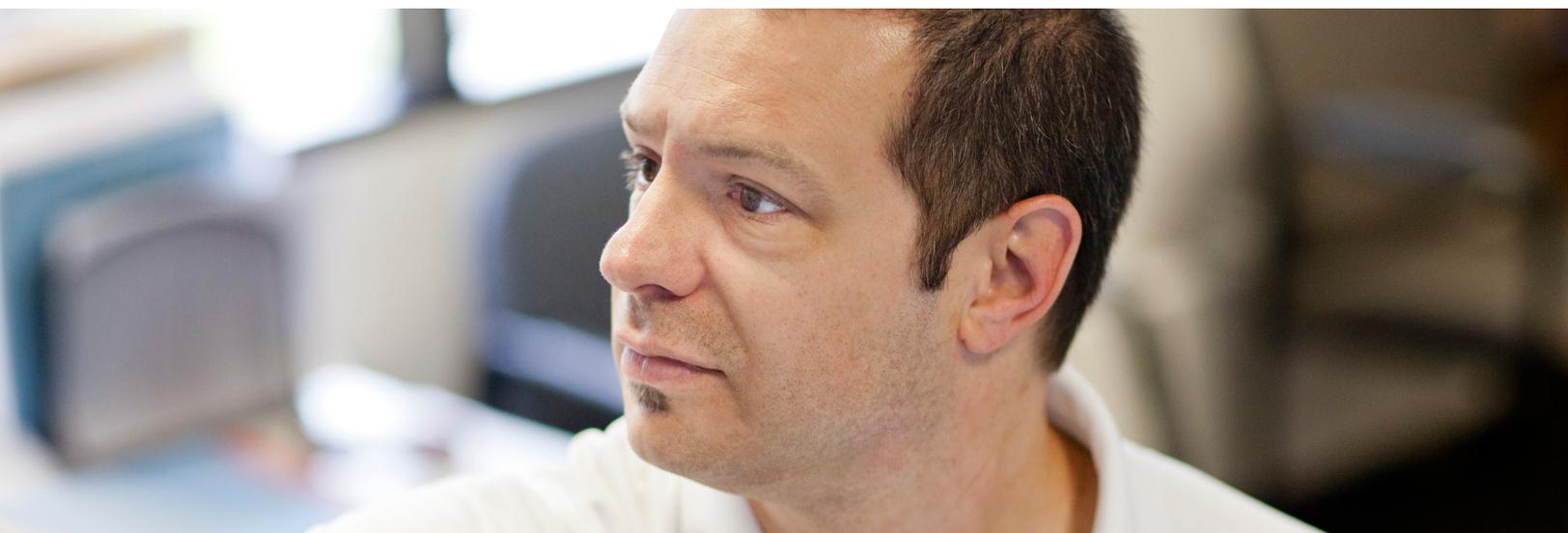
Successful sales strategies can come not only from reimbursement, but also from a well-defined value proposition.

oversight and strict patient selection criteria are often not representative of real-world patient populations. Conduct of Class 2 studies provides greater insight into the costs, benefits, and patient outcomes a new device may have. Too often, companies fail to plan for health outcomes studies. Mandated postmarket surveillance should not be the only reason companies have for collection of post-approval data. The need for postmarket surveillance can typically be leveraged into valuable health outcomes and value proposition data if properly considered.

Publication Planning: Getting Your Data Out

Dissemination of data needs to be planned and carefully considered early in the product development process. Publication planning will ensure the necessary data are released in an ethical and timely fashion while reaching your desired audience. Peer-reviewed journal publications are the preferred method of dissemination of clinical and economic data regarding a new medical device. Journal publications provide a level of credibility to the data and technology that cannot be realized by internal white papers. CMS, private payors, hospitals, and physicians expect data to be presented in the form of journal publications. Release of abstracts and podium presentations at society meetings are also valuable dissemination tools. Including publication planning, authorship considerations, and medical writing early in the process of product development will result in maximum use of clinical data. Early planning also helps determine the role of KOLs and other physician activities in the dissemination of data. In addition, proper publication planning can identify the key journals and conferences to effectively reach your targeted healthcare providers. Beginning this process early is crucial for success as the type of clinical trial design and prospective data analysis performed may limit your access to top-tier journals.

The necessary relationship between physicians and medical device companies is of vital importance, but also creates additional regulatory considerations once a device is cleared for sale. Acceptance of your product within the medical community is necessary to drive sales, regardless of reimbursement. The best way to achieve broad acceptance of your device, as noted above, is by having your product presented at medical society meetings and outcomes data published in medical journals. In order to do this you need physicians to support your product and data collection efforts. While physicians are not



allowed to be paid for authorship, companies can pay expenses for meeting attendance, time for steering committee or advisory committee involvement, and device development work. If you are fortunate to have your product reimbursed by CMS, be aware that you are required to report all physician payments under the Sunshine Act.

Implications of the Sunshine Act for Medical Device Companies

In February of 2013, the Sunshine Act was passed by Medicare. This Act applies to all device manufacturers that obtain reimbursement for their product. As part of increasing transparency within CMS, manufacturers are required to submit annual reports to CMS on how much they spend on various physician and continuing medical education activities. Companies are required to have procedures in place to account for and track such spending by August 2013, and reporting will be required by all qualifying companies starting in 2014.

Enactment of the Sunshine Act has direct implications for medical communications and clinical data collection activities that are necessary to ensure strong sales. Keeping up with the new requirements will both ensure acceptance in the medical community and document ethical responsibility, thus demonstrating transparency. Without adequate plans and actions for complying with the Sunshine Act, companies risk negative customer impact because of 1) flawed reporting (whether intentional or not), 2) financial penalties that can range up to \$1,150,000, and 3) legal conflict. The new requirements may be expensive, time-consuming, and require considerable procedural adjustment. While the vast majority of firms will most likely be in compliance already, it requires significant changes to how

Planning for Successful Medical Device Reimbursement: So Your Device is Cleared, Now What?

companies document their interactions with healthcare providers. Early planning and incorporation of systems and methods for recognizing and tracking the necessary financial information to ensure complete reporting into post-market activities will be key. Such action will allow your company to maintain a good reputation among customers and promote company growth and devices sales, instead of accumulating financial penalties and unnecessary legal/ethical conflicts that could obstruct the sale of a good medical product.

Conclusion

Innovation is the cornerstone of medical advancement and improving health outcomes. Just like no two devices are alike, no two strategies for successful launch and continued success of commercial distribution are the same. Incorporating reimbursement and publication strategies early in the product development process are necessary to ensure that a great technology is not just available for use but is actually used, and used by patients who can most benefit from it. By planning ahead you can maximize clinical activities and physician relationships while maintaining high ethical and regulatory standards.

“Everything we do must be in our clients’ best interests.”

Ted Gorski, NAMSA Founder

Throughout our 46 year history NAMSA has assisted thousands of companies around the world in translating their great ideas into medical products for the patients who need them most.

Our regulatory strategy, testing services, quality system consulting, clinical research, and sterilization products support the medical product development process. With NAMSA’s MRO™ approach to testing and consulting, you maintain project control while gaining the benefit of on-demand external support: extending your in-house capabilities, accessing specialized expertise at exactly the right time, or having a completely outsourced development process.

NAMSA®