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Medical Device Reimbursement Strategy: How to Plan for Successful Market Commercialization

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Not long ago, the U.S. Food and Drug Administration (FDA) clearance process was the golden ticket for successful commercialization of new medical technologies in the United States, a route that many companies put significant energy and resources into. However, this has shifted dramatically over the past several years, attributable in part to the Patient Protection and Affordable Care Act (PPACA) of 2010—or what is often referred to as 'Obamacare'.

While there have been many recent changes surrounding PPACA, hospital system consolidation, physician mergers and foundational changes—in addition to the manner in which health care is delivered today—the industry shows no signs of shifting to the pre-PPACA paradigm. As a result, medical technology companies must understand the impact of value-based purchasing, alternative payment models and hospital and physician incentives in order to position their technologies for market success.

In other areas of the world, particularly within the European Union (EU), significant shifts have also been observed surrounding healthcare reimbursement. For example, the European Network for Health Technology Assessment (EUnetHTA) is leading an initiative to supply prospective and timely advice to improve the quality and appropriateness of data produced by medtech companies. The hope is that improved quality of data will lead to better-informed regulatory and reimbursement decisions—not unlike the FDA's/Centers for Medicare and Medicaid's (CMS) Parallel Review Process or Comparative Effectiveness Research in the U.S.

Given the many considerations above, a carefully developed reimbursement strategy that appropriately addresses current market dynamics is fundamental to successful device commercialization. This White Paper seeks to identify many of these demands as global device manufacturers look to better manage increasing costs for aging populations amid frequent technological innovations, while also addressing rising pressures of government and employer healthcare budgets.

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About the Author

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Edward Black specializes in reimbursement strategy, payer relations and health economics for medtech and biotech companies in the U.S. and abroad. He works with medical device organizations to commercialize new products and services through successful reimbursement planning.

Prior to joining NAMSA in 2018, Mr. Black founded Reimbursement Strategies, LLC in 2008, a medtech consultancy focused on reimbursement services including HCPCS and CPT coding analysis and new code submissions; medical coverage policy research, analysis and advocacy; payment negotiation; clinical trial optimization for reimbursement; and health economics for new and existing technologies.

Mr. Black also has 25 years' experience in health and provider network management within the Blue Cross Blue Shield (BCBS) healthcare system, and served on two national advisory boards responsible for leading consistency in medical, benefit and payment policies. From 1994 to 2002, Edward served as the Executive Director of three managed care business partnerships with large multispecialty clinics for which he was honored with the 1995 Outstanding Contribution to the Healthcare Industry Award by Medical Alley Association.

Mr. Black is active in several global medical technology initiatives and is a frequent international lecturer. He serves as an adjunct faculty member of the University of Minnesota Master of Science in Medical Device Innovation Program, and is a Reimbursement Advisor to the University of Minnesota Office for Technology Commercialization and National University of Ireland Galway BioExel Program.

Coding

Coding is the common language among healthcare providers and payers for new and existing technologies. Healthcare Common Procedure Code System (HCPCS) code evaluation is often the first step in evaluating the commercial viability of a new technology. Current Procedural Terminology (CPT™) codes, also known as Level I HCPCS codes, define professional healthcare medical, surgical and diagnostic services. These codes are trademarked and controlled by the American Medical Association (AMA), and their approval is subject to close scrutiny by multiple medical societies whose interests occasionally conflict. HCPCS Level II Product Coding is controlled by CMS.

Within CPT, there are Category I and Category III codes.

While cost-effectiveness analyses are most useful, budget impact, cost minimization, return on investment and quality of life studies can be beneficial when presenting justification to serve various stakeholders.

- Category I codes are reserved for new procedures and require considerable clinical evidence and the support of one or more medical societies whose physicians would most likely use the device.
    - The process for Category I coding approval can take anywhere from three to five years, and is often complicated due to competing interests of medical societies.
    - Services defined by a Category I codes are more likely to secure coverage.
- Category III codes are reserved for new and emerging technologies, primarily to track utilization and data points.
    - Requirements for Category III coding are lower, but services represented by these codes are rarely covered and paid.
- Medical device manufacturers must make important strategic decisions regarding CPT coding early in the device development process as they will have a significant impact on the design of clinical trials.

HCPCS Level II codes exist to define items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). CMS tends to have a bias to squeeze as many products as reasonable into existing codes in order to maintain a practical, manageable database. New products must be different in design, function and purpose in order to qualify for a new code. Each HCPCS code is attached to a national fee schedule which can either be very beneficial or quite disadvantageous. A new device will be assigned to an existing HCPCS code descriptor, if fitting, creating a critical reason to understand the economics of device payment before determining final medical device design.

While hospitals are obligated to use HCPCS codes for outpatient services, they report procedures in nomenclature described in the International Classification of Diseases-Tenth Edition, Procedure Code System (ICD-10 PCS) for inpatient hospital services. Clinical Modification (ICD-10 CM) is the standard code set used by all providers to describe diagnoses and symptoms.

Further complicating the coding process is the fact that changes to coding schemes occur annually. When the procedure codes align with proper diagnoses codes—and the services are covered—device manufacturers are in business. However, when they do not align, device makers face many reimbursement challenges.

Payment and Health Economics

The difference between payment and health economics can be somewhat confusing as government (e.g., Medicare, Medicaid, TRICARE and Veterans Health) and commercial insurers have long-established methodologies by which payment levels are calculated for new technologies.

Payments typically vary by the setting in which services are provided (i.e. hospital inpatient, hospital outpatient, ambulatory surgery center, skilled nursing facility, clinic and home). Most government and commercial insurers abide by these common methodologies, but payment rates vary widely which leads providers to rightly be concerned about payer mix—another measurable dynamic that can drive or destroy adoption.

Appropriate understanding of payer mix and payer rates can be challenging due to the fact that:

- Inpatient hospital services are paid according to Diagnosis Related Groups (DRGs)
- Outpatient hospital services are paid under a system termed Ambulatory Payment Classifications (APCs)
- Ambulatory surgery centers are paid on a fee schedule
- Clinics are most commonly paid on a fee-for-service basis known as Resource-Based Relative Value System (RBRVS)
- DMEPOS are paid on a fee schedule
- Labs services are paid on a fee schedule

Medical device manufacturers must realize that these standardized methodologies are used to determine specific monetary allowances for new devices, which are based in small part on user cost, but more importantly on how and where they will be utilized. For example, a new device may be profitable for a provider in a hospital outpatient setting, but unaffordable in an ambulatory surgery center.

In many instances, a strong health economics case is required for health plan coverage, even though it may have little effect on pricing. While cost-effectiveness analyses are most useful, budget impact, cost minimization, return on investment and quality of life studies can be beneficial when presenting justification to serve various stakeholders. Similar to clinical evidence, insurers will carefully screen for industry bias in health economic studies, especially when they are company-sponsored.

Coverage

Of all reimbursement barriers, coverage presents the biggest hurdle for medtech organizations. Simply put, there are no standards for how much or what types of clinical evidence are required to secure favorable medical coverage policy. While government and commercial health insurers typically make their own coverage decisions, there are regional jurisdictions administered by different Medicare administrative contractors who determine their own medical policy decisions through Local Coverage Determinations (LCDs). Consequently, Medicare beneficiaries in Texas may be covered for certain technologies that are not covered in Pennsylvania, and vice versa. Another unique caveat related to coverage is that the decision-making process among commercial insurers can be even more variable.

While the FDA operates under the principles of "safe and effective," Medicare policy is guided by the standards of "reasonable and necessary." Not every medical service that is judged to be safe and effective is considered reasonable and necessary for covered patient care.

The clinical evidence required for FDA clearance or approval should be considered as a baseline standard for reimbursement. However, there is a prescribed, higher set of clinical criteria to obtain CPT codes; requirements for coverage are higher, have no standards and vary widely among government and commercial insurers. Point blank: insurers want evidence—they don't want to be pressured by manufacturers' representatives and will rarely meet with them.

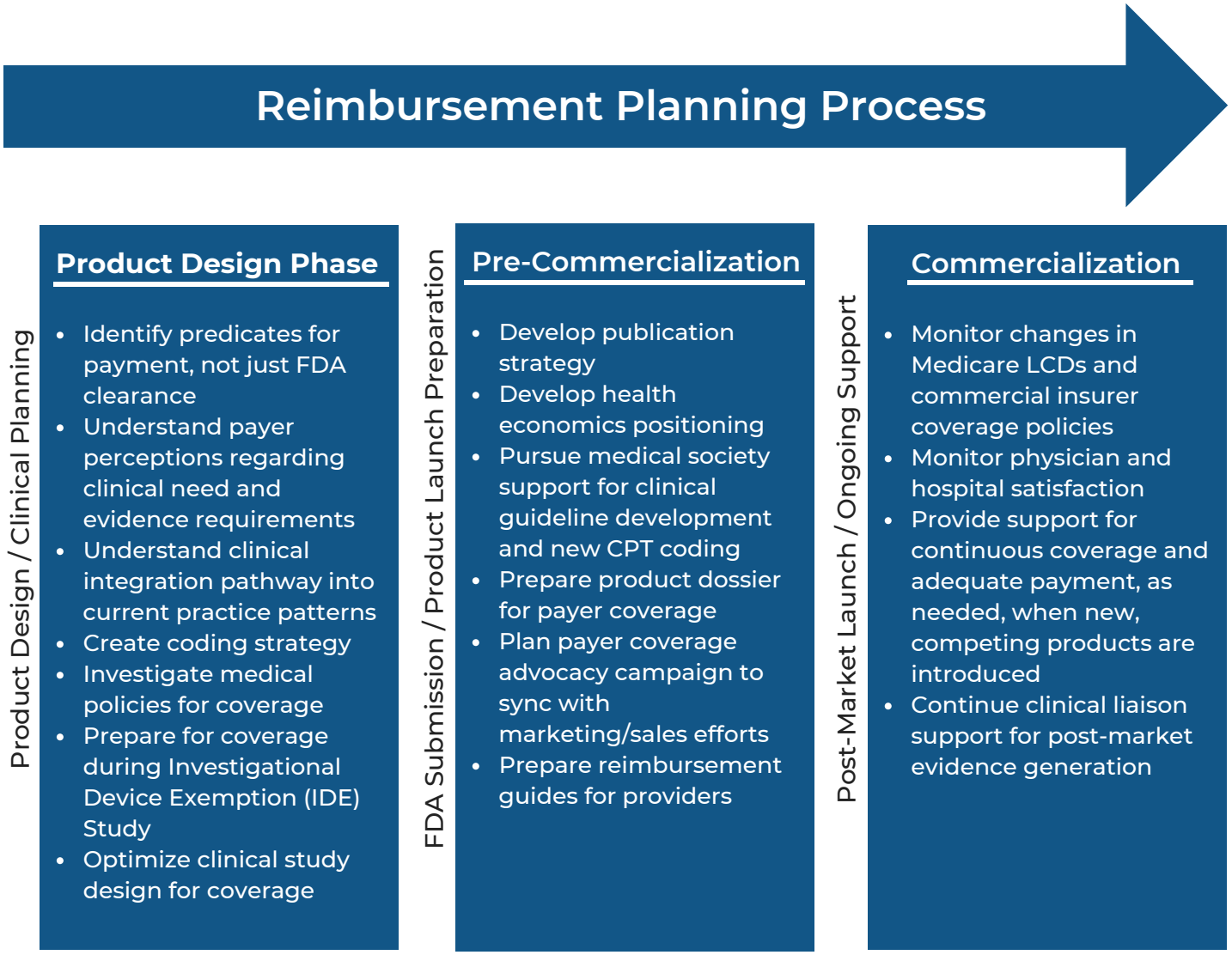
Bridging the Gap between Device Stakeholders

A Medical Science Liaison Officer (MSLO) has long been a highly valued position within pharmaceutical companies. This role is designed to bridge the gap between the manufacturer's perspective, medical science, healthcare professionals, patients and payers—and is usually filled by someone with an MD or PhD degree in a medical science profession. Because of the constantly changing landscape in healthcare, the MSLO role has expanded to the medtech and biotech industries.

Using an MSLO in the reimbursement process is an efficient way to maximize medical expertise to communicate with payers and present data in a more objective, clinical manner with less perception of company bias. Health plan medical policy personnel should not be underestimated as they can immediately differentiate a sales/marketing expert from a clinical leader. For instance, sales/marketing experts have little credibility while clinical experts can speak in an unbiased manner regarding medical coverage policy—thereby maximizing success in representing new technologies or existing technologies for new clinical applications. This is a bridge that non-clinicians cannot consistently cross.

The Reimbursement Planning Process

The process for reimbursement planning occurs in several stages of development due to the many variables previously discussed. In some cases, reimbursement planning can begin in the product design phase and extend through product maturation.



Planning early in the design phase is critical because products and services designed for one service setting may not be covered or profitable in another. Many products in the design phase already have a pre-determined reimbursement pathway and may be locked into a payment category and level—entrepreneurs and investors need to understand where they fall in this spectrum early on.

Reimbursement Considerations within Regulatory, Clinical and Marketing Planning

Integrating reimbursement planning within regulatory, clinical and marketing processes is crucial. When the option to choose among predicates for regulatory purposes arises, medical device manufacturers are wise to identify higher paid comparators.

If a technology requires unique CPT or Level II product coding, device makers may design a series of clinical evidence that can satisfy both FDA and new code requirements. Furthermore, dependent on the degree of device novelty, additional and varied types of clinical and health economics evidence should be accounted for early in the process. This is required to maximize clinical design resource efficiency and speed-to-market.

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An important final note is that medical device sales teams should be aware of the territories in which a device is covered, as new technologies cannot be successfully adopted in areas where devices are not reimbursable.

Conclusion

Requirements for coding, payment and coverage must be incorporated into the broader planning process, particularly as they relate to reimbursement strategy under PPACA. Medical device organizations without a carefully thought-out reimbursement strategy will ultimately lack a fully developed business plan and will run the risk of non-adoption and market failure. Manufacturers must plan early and coordinate carefully to be successful long-term.

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About NAMSA

NAMSA is a Medical Research Organization (MRO®), accelerating medical device product development through integrated laboratory, clinical and consulting services. Driven by our regulatory expertise, NAMSA's MRO® Approach plays an important role in translational research, applying a unique combination of disciplines—consulting, regulatory, reimbursement, preclinical, toxicology, microbiology, chemistry, clinical, and quality— to move clients' products through the development process, and continue to provide support through commercialization to post-market requirements anywhere in the world.

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