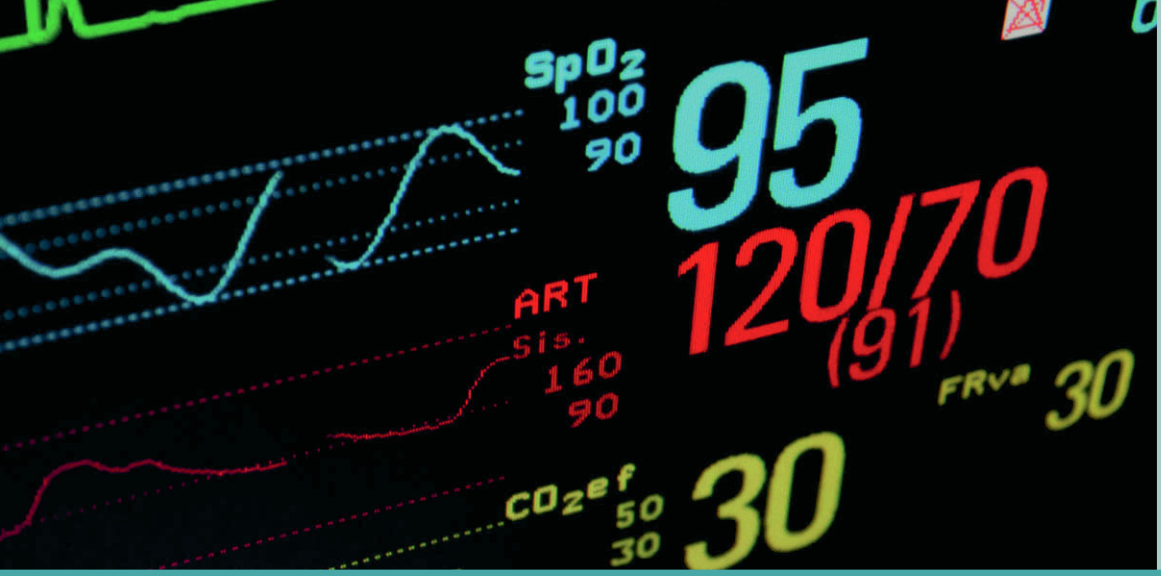

5.6 Reimbursement Strategy

INTRODUCTION

The good news is that the technology the team has developed is a true breakthrough, with the potential to help millions of patients worldwide. And it is likely to save money for the healthcare system in the long run through reduction in hospitalizations and long-term medical management costs. The issue – and it is a big one – is that there is no existing code for reimbursement in the US. The team has a reasonably clear plan for the PMA pivotal trial, but the daunting job ahead is to develop a strategic approach to gaining reimbursement from Medicare and key private payers. The reimbursement consultant is experienced and savvy, but she has been clear in pointing out that the reimbursement environment is evolving in dramatic and unpredictable ways.

The commercial success of any medical technology depends on a company's ability to get adequately paid for providing it to its target customers. Yet, there is no question that the reimbursement landscape is becoming universally more challenging. Across geographies, payers of all types are increasingly asking companies to prove the economic value of their offerings, not just their clinical benefit. In the US, the healthcare system appears to be evolving toward payment systems that explicitly reward value, yet the current environment remains dominated by fee-for-service payments and still features conflicting financial incentives for different stakeholders. The ability to navigate these types of challenges with a successful health economic and reimbursement strategy can be a critical factor determining the success or failure of the technology.

Chapter 4.3 Reimbursement Basics provides foundational information about assessing the reimbursement landscape in the US to determine how a new solution might fit in to existing coding, coverage, and payment paradigms. This chapter focuses on the processes required to expand the payment infrastructure to accommodate a new device if the established reimbursement is inadequate. It also explores the key ingredients for creating a comprehensive reimbursement strategy.

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OBJECTIVES

- Understand the steps and timing involved in pursuing relevant codes, appropriate coverage determinations, and adequate payment rates for new technologies.
- Learn some of the important strategies for dealing with the Centers for Medicare and Medicaid Services (CMS) and private insurers in the US, and with comparable payment agencies abroad.
- Appreciate the elements of a reimbursement strategy and how to coordinate its development with other functions, including R&D, marketing, and clinical research.
- Recognize the emerging importance of economic value calculations in gaining reimbursement (in the US and abroad).

REIMBURSEMENT STRATEGY FUNDAMENTALS

If a new technology comfortably fits within existing **coding**, **coverage**, and **payment** constructs within its target markets, a company has a distinct advantage. If not, the first step in devising a **reimbursement** strategy is to prepare to systematically pursue appropriate *coding*, a positive *coverage* decision, and a favorable *payment* level for the offering (see chapter 4.3 for an introduction to these three key concepts).

Expanding reimbursement for a new technology

Understanding the steps required to obtain reimbursement approval from Medicare in the US is a useful starting point for determining how to approach this challenge.

Coding

In pursuing coding for a new technology, the company must choose a specific course of action based on the type of code that is needed and its purpose. The two most relevant sets of procedural codes are the **ICD-10 codes** used by hospitals in the inpatient setting and HCPCS codes for services and equipment provided in the hospital outpatient and ambulatory surgery center settings, as well as all physician services. ICD-10 diagnosis codes are used by facilities and physicians to record patient symptoms and diagnoses on health insurance claims in all sites of service.

ICD-10 codes for hospital inpatient claims[1] For *inpatient* procedures, hospital billing is based on the identification of appropriate diagnoses and procedures from the ICD-10 code sets.[2] Responsibility for maintaining the ICD-10 codes is divided between two agencies. The National Center for Health Statistics (NCHS) within the Centers for Disease Control and Prevention (CDC) maintains the classification of diagnoses; **CMS** maintains the classification of procedures. The ICD-10 Coordination and Maintenance (C&M) Committee, co-chaired by representatives from NCHS and CMS, reviews requests to create new ICD-10 codes or to revise existing codes. The C&M Committee holds public meetings twice a year (usually in March and September), to discuss proposed revisions and solicit public comments. The C&M Committee's role is advisory – no decisions are made at these meetings. The Director of NCHS (for diagnoses) and the Administrator of CMS (for procedures) make all coding decisions.

Requests for coding modifications are accepted from both the public and private sectors.[3] Interested parties are instructed to submit recommendations for ICD-10 modification to the C&M Committee two months prior to a scheduled meeting. Proposals for new codes should include background information on the procedure, patients on whom the procedure is performed, outcomes, and any complications. In addition, the proposals should describe the manner in which the procedure is currently coded, the reasons the existing ICD-10 codes do not adequately capture the procedure, a description of the requested code, and recommended options for a new code title. Supporting references and literature can be included.

The C&M Committee reviews each proposal and decides which ones to include on the C&M meeting agenda. A lead coding analyst is assigned to each selected proposal. This individual contacts the requestor prior to the meeting to discuss the proposal and then prepares and issues a background paper, which includes recommendations on the suggested coding revisions. (Example code papers can be found in the summary reports from previous C&M meetings online.) In the meeting, the requestor is then given the opportunity to make a 20-minute presentation on the clinical nature of the procedure. The lead coding analyst then conducts a discussion of possible code revisions, including alternative suggestions for consideration. CMS makes its final decisions based on this discussion, as well as public comments. Code revisions generally become effective October 1 of the following year.

HCPCS Level I (CPT) codes for hospital outpatient and physician claims As described in chapter 4.3, the **HCPCS** system consists of two levels of codes. The first type, **Level I codes**, are called Current Procedural Terminology (**CPT**) codes, which are used by hospitals in

the *outpatient* setting and by medical professionals (e.g., physician claims) in all settings of care. CPT codes are established and maintained by the American Medical Association (**AMA**).

If existing CPT codes are inadequate (or non-existent) for describing a new technology-related procedure for the purpose of physician and physician practice reimbursement, the company can either seek to have a new code created or an existing code modified. In both scenarios, an application must be submitted to the American Medical Association (AMA). However, rather than being submitted to the AMA directly by the company, applications are typically sponsored and managed by an appropriate professional society of physicians willing to advocate for the new code. Fundamentally, the application and supporting data for a new, permanent CPT code (called a category I code) must demonstrate that:[4]

1. All devices and drugs necessary for performance of the procedure or service have received **FDA** clearance or approval when such is required for performance of the procedure or service.
2. The procedure or service is performed by many physicians or other qualified healthcare professionals across the United States.
3. The procedure or service is performed with frequency consistent with the intended clinical use (i.e., a service for a common condition should have high volume, whereas a service commonly performed for a rare condition may have low volume).
4. The procedure or service is consistent with current medical practice.
5. The clinical efficacy of the procedure or service is documented in literature that meets the requirements set forth in the CPT code change application.

Proposals to add, modify, or delete CPT codes are considered by the CPT Editorial Panel, which includes representatives from the AMA, private health insurers, the American Hospital Association, the Health Care Professionals Advisory Committee, and CMS. This group is supported by the CPT Advisory Committee, comprising representatives of more than 90 medical specialty societies and other healthcare professional organizations. The CPT Editorial Panel meets at least three times a year. Applications for new codes are accepted on an ongoing basis but must be received at least four months in advance for consideration at the next meeting. An application form and directions to request CPT changes are available on the AMA website. Category I CPT codes are updated annually to reflect changes in medical technology and practice, with the coding changes taking effective on January 1 of each year.[5]

In the majority of cases, the AMA will not approve a new, permanent CPT code until **pivotal trials** have been performed and the results published, FDA approval/clearance has been granted, and there is evidence of widespread adoption. For most companies, this means that their code application efforts cannot begin in earnest until the product is launched (although planning of the reimbursement strategy must commence much earlier, as described later in the chapter). Once the product is in the market, it can take considerable time and resources for the company to drive adoption and to perform additional studies that may be required to justify code creation or revision. In total, this process can take from three to six years, depending on the device, study design, follow-up period, and journal publication schedule. After evidence is collected and submitted to the AMA, the company might wait an additional one to two years while the AMA reviews the coding change request and makes a determination. For example, it took Metrika (the company with the point-of-care hemoglobin A1C (HbA1C) test for diabetes patients described in 4.3 Reimbursement Basics) seven years from the time of FDA approval to receive an adequate CPT code and payment level. In contrast, companies producing other technologies, such as transcatheter valves, have successfully worked together with medical societies in parallel with the FDA process to obtain permanent CPT codes less than two years after regulatory approval. Importantly, companies must remember that, despite their decision to invest in this lengthy process, there is still no guarantee that the AMA will approve their coding requests.

The AMA assigns CPT codes in three categories (see Table 5.6.1). Most CPT codes that qualify for reimbursement are permanent category I codes, which fall into one

Table 5.6.1 Different categories of CPT codes are used for different purposes.[6]

CPT code category	Description	Usage
Category I	Codes for procedures and services that are consistent with contemporary medical practice and widely performed.	RVU value and payment is established for procedures and services that have a category I code.
Category II	Supplementary tracking codes that can be used for performance measurement.	No payment attached. Used strictly to facilitate data collection. Not relevant for **medtech** reimbursement.
Category III	Temporary codes for emerging technologies, services, and procedures.	Used to facilitate data collection while an innovation is being evaluated. Associated payments must be negotiated with each individual payer.

of six sections (evaluation and management, anesthesiology, surgery, radiology, pathology and laboratory, and medicine).[7] For category I codes, CMS typically assigns a national Medicare physician fee schedule payment amount for the service and most private **payers** also use this for the purposes of establishing physician payment. Category II codes, applied for and used by health systems to document and monitor quality practices, are not applicable to device reimbursement. Category III codes are for new and emerging procedures. They can be obtained before FDA approval or widespread adoption and are typically used as intermediate codes to track usage and establish the need for a permanent category I CPT code. If a company applies for a category III code, it does so to build a history of widespread usage so that the category III code can eventually graduate to category I.[8] Payers usually do not have fixed fee schedule payment levels for category III codes, but instead determine payments for these codes on a case-by-case basis.

Many companies apply for a category III code as an interim step in obtaining a category I code. While the path to securing a category III code can require less supporting evidence, it is important to reiterate that it does not always have payment linked to it[9,10] and can flag the procedure as experimental, potentially disqualifying it for coverage by some payers. Strategies that include category III CPT codes should be carefully evaluated with the help of reimbursement consultants.[11]

Category III codes usually take up to six years to become category I codes (and thereby trigger payment). Historically, some highly compelling technologies have moved from a category III code to a category I code more quickly. For example, Conceptus Inc. applied for a category III code for its Essure device, which received FDA approval in late 2002 for the minimally invasive treatment of blockages in the fallopian tubes. The company's plan was to use the category III code while it worked to build adoption. However, based on the strong **quality of life** and cost savings data submitted with its application, the AMA instead granted a category I code only two years after FDA approval. More recent examples of technologies that were rapidly converted from category III to category I include transcatheter aortic valve replacement systems, percutaneous mitral valve repair systems, and subcutaneous implantable cardioverter defibrillators.

Another, more common approach to billing for devices and procedures that do not yet have a category I CPT code is to temporarily use a miscellaneous CPT code. Miscellaneous CPT codes, which are grouped by anatomical system and procedure type can be used when "there is no existing national code that adequately describes the item or service being billed."[12] Their advantage is that they can be used as soon as a new procedure is approved by the FDA and while the company is applying for a permanent code. The disadvantage is that claims with miscellaneous codes typically require more detailed

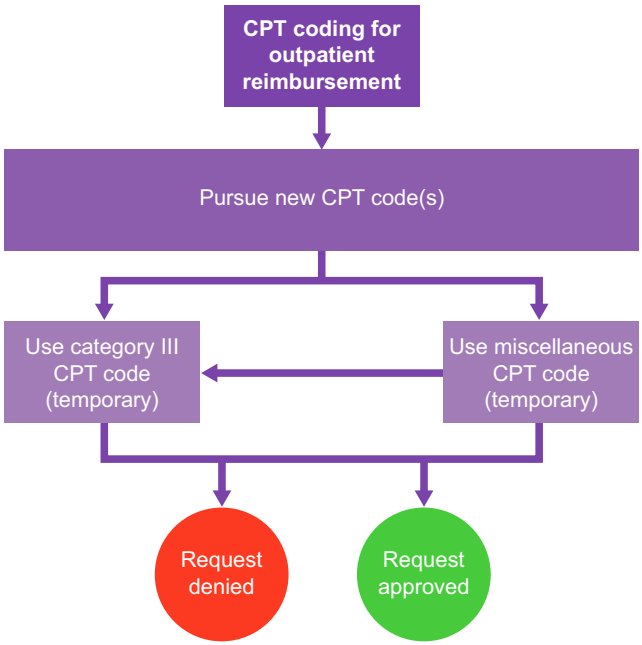

FIGURE 5.6.1
When pursuing a new category I CPT code, companies can seek category III codes and/or use miscellaneous codes to help them build their case.

documentation than usual claims and are often manually reviewed by Medicare and other payers. Therefore, it is to the manufacturer's benefit to closely monitor and support the process of providers submitting these claims so that they are reliably reimbursed at adequate levels. Failure to appropriately support the process may set a bad precedent that affects the reputation of a new device if claims are routinely denied or payments are inadequate.

Often, a company will recommend to hospitals and physicians that they use a miscellaneous code initially, while the company seeks creation of a category III code (with the intent to convert as quickly as possible to a category I code upon FDA approval) or a category I code (after FDA approval). This approach can accelerate reimbursement of the company's device as it seeks to build adoption. However, optimal strategies will depend on the specific technology, and companies are advised to seek input from a qualified reimbursement expert.

Figure 5.6.1 summarizes the CPT coding pathways available to medtech companies.

HCPCS Level II codes for outpatient claims[13] **HCPCS Level II** codes are used primarily to submit claims for products, supplies, and services *not* included in the CPT codes. These codes apply to durable medical equipment, prosthetics, orthotics, and supplies (as well as drugs and biologics). A descriptor is assigned to a code that provides the definition of the items and services that can be billed using that code.

The permanent national HCPCS codes are distributed and maintained by CMS. Permanent codes fall into one of 11 code sets (e.g., E codes are for durable medical equipment; L codes are for orthotics and prosthetics). The CMS HCPCS Workgroup considers each coding request at its regularly scheduled meetings and recommends whether a change to the national permanent codes is warranted based on factors such as the uniqueness of an item's function and operation, its therapeutic distinction relative to existing coded treatments and products, and how it compares to defined volume and marketing criteria.[14] CMS makes the final HCPCS coding decisions. The permanent national codes are updated once a year on January 1.

Temporary national HCPCS codes are also maintained and distributed by CMS. Temporary codes allow CMS the flexibility to establish codes that are needed to meet the national program operating needs of a particular insurer (i.e., Medicare, Medicaid, private insurance sector) before the annual update for permanent national codes or until consensus can be achieved on a permanent national code.

The CMS HCPCS Workgroup has designated certain sections of the HCPCS code set for temporary codes for specific items or types of insurers. For example, G codes are used by Medicare to identify professional healthcare procedures and services that would otherwise be coded in CPT but for which there are no suitable CPT codes. Medicare also uses C codes for certain outpatient items and services, including pass-through devices. (For more information about transitional **pass-through payments**, see the section on hospital outpatient payments later in this chapter.)

Temporary codes do not have fixed expiration dates, and they can be added, changed, or deleted on a quarterly basis. Once established, temporary codes for Medicare are usually implemented within 90 days.

Coding and private payers Codes set up by the AMA (CPT codes) or CMS (ICD-10 and HCPCS Level II) are also used by private payers. If there is a long delay before unique codes are issued, private payers may ask providers to use an existing code to bill services in the interim, agreeing on expanded coverage and/or payment terms under that code. In many cases, private payers would rather have providers use a unique code, even if it is not the permanent code, so that they are able to track and monitor usage and more efficiently process claims. Private insurers use S codes to report drugs, services, and supplies for which there are no permanent national codes, but for which codes are needed to implement policies, programs, or claims processing.

Coverage

In order to obtain reimbursement, a new procedure must gain coverage from payers, either through explicit coverage policies issued by the payer or implicitly based on a payer's determination that it falls within a defined insurance benefit and is "medically necessary" for the insurer's enrollees. Coverage decisions can be favorable, negative, or limited, and may be formalized within a policy or informally addressed on a case-by-case basis.

When making coverage decisions, payers typically seek information about the following key criteria:

- Final approval from the relevant government body (for example, the FDA in the US, **CE mark** in other countries).
- Evidence that proves non-inferiority (and ideally, superiority) on safety and effectiveness compared to currently available treatments that are covered services.
- Data to support favorable health outcomes and clinical improvement in the real world (not just in an investigational setting).
- **Peer-reviewed** evidence published in a (preferably high-impact) journal. For US payers, studies conducted in other countries will be less impactful.
- Published clinical practice guidelines and health technology assessment reviews.
- Specialty society endorsements or positions regarding reimbursement.

When seeking coverage from Medicare, companies can pursue one of two different approaches: (1) a national coverage determination (**NCD**); or (2) a local coverage determination (**LCD**). NCDs are made by CMS and apply to beneficiaries across the country (companies can seek meetings with CMS coverage staff to obtain informal guidance regarding Medicare coverage issues). LCDs are made by Medicare Administrative Contractors (**MACs**) and apply to beneficiaries in their jurisdictions (which typically span one geographic area, although some contractors cover multiple states across the country).[15] Currently, CMS has nine MACs that cover 14 jurisdictions. Because claims adjudication takes place at the local level, providers and companies must negotiate with local contractors, especially in the launch phase of a device (see below) and different LCDs may be in place for the same device under different contractors.

Local coverage determination Requests for an LCD for a medical device are often submitted by local providers, a professional society acting on behalf of the company, and/or reimbursement staff or consultants. Medical professionals among the Medicare contractors tend to have strong personal relationships with the local medical community. These relationships can be leveraged by the company as part of the LCD process. When making an LCD, a local contractor will consider a variety of inputs, including the results of a literature review, medical evidence submitted, physician testimony, and the outcome of existing systematic reviews (such as technology assessments). Once a recommendation has been made, a final review by the contractor-based carrier advisory committees (**CAC**) is mandatory for all proposed local coverage decisions. CACs are made up of practicing physicians representing multiple specialties. Proposed LCDs are posted on the CAC website for 90 days so that public and CAC comments can be collected as input to the final decision. Once a decision is implemented, the coverage policies can be revised or expanded whenever new, sufficiently compelling evidence is presented to justify a change. Furthermore, LCDs are non-binding – so "one-off" rulings are often made at the contractor level. For example, local contractors may allow one-time

access and/or deny or pay claims for interventions that preceded local coverage decisions.[16]

Typically, company representatives and/or local physicians pursuing an LCD will visit the appropriate local Medicare contractors at launch in order to secure a coverage commitment for their new technology and associated services using miscellaneous and temporary codes. Until these efforts lead to favorable, published coverage decisions, confusion can exist among providers as claims are potentially denied or underpaid – a common occurrence during the early stages of a local coverage determination. Additional confusion can be caused by the fact that LCDs are not binding, can change at any time, or be highly inconsistent across the country. The rework associated with this uncertainty places a significant administrative and financial burden on the providers that attempt to use the new technology. Reimbursement strategies that include LCDs require the company to build and sustain strong local advocacy and relationships with providers, a relatively large reimbursement team to help manage issues, and persistence in working with local contractors. Success at the local level is most often achieved through a series of small wins, with all favorable policies requiring ongoing maintenance by the company.

National coverage determination CMS issues a limited number of NCDs each year. Most coverage decision making still occurs at the local level by local Medicare contractors. NCDs are primarily used for products and services that may have a significant health and/or budgetary impact on the Medicare program. **Cost-effectiveness** is not explicitly a factor that CMS considers in making NCDs, although CMS informally takes into account the anticipated budgetary impact to the Medicare program in its decision-making process. In order to aid these decisions, CMS sometimes convenes a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), consisting of outside experts to provide advisory input on specific topics either before or during an NCD coverage review. Companies are strongly advised to seek input from physician key opinion leaders (**KOL**s), professional societies, and/or reimbursement consultants in determining an appropriate coverage strategy.

In some cases, companies may seek an NCD even when the LCD option is possible to avoid the inconsistencies and confusion that can be associated with multiple LCDs. Innovators are strongly encouraged to meet with CMS officials before making a request for an NCD. If a decision is made to pursue national coverage, a written request should be submitted that meets published CMS requirements. This request could be submitted by the manufacturer, a medical society, or initiated internally by CMS.

Although there are many benefits associated with an NCD, this is not a realistic strategy for all companies to pursue. Normally, CMS will only consider NCD requests for a device or intervention that shows breakthrough potential in terms of its clinical benefits and/or cost-effectiveness. CMS may also make an NCD for highly controversial technologies that it deems to be unsuitable for individual rulings by the local contractors (in these cases, CMS can trigger an NCD internally, without a request from the company).[17] Furthermore, CMS typically will only consider an NCD for innovations where there is a large potential budget impact to the Medicare program, significant controversy around the clinical **value** of the treatment, substantial inconsistencies in local coverage by MACs, or some combination of the above. The process of pursuing an NCD can also be extremely time-consuming and resource-intensive, making it infeasible for most small device start-ups. Without the resources of a large company to devote to the pursuit of a NCD, this approach is considered highly risky. A much safer model is to use a series of LCDs to build a basis for national coverage.

NCD versus LCD When considering whether to pursue an LCD or an NCD, there are several other factors that a company should keep in mind. First, even with a published NCD issued by the CMS national coverage group, actual payment rates are established under a separate decision-making process by CMS payment staff according to national payment systems for each setting of service. This means that a sizable effort may still be required, working with CMS payment officials at the national level to secure favorable payment terms. Second, NCDs can be problematic in that they are

binding national decisions that can result in unfavorable and often irreversible policies toward the company. For example, in 2005, the FDA approved a vagus nerve stimulation (VNS) device manufactured by Cyberonics for depression in patients who had failed other treatments. Though the device was previously approved and covered for epilepsy, the value of the procedure for depression remained controversial. At a cost of roughly $30,000 for the device and implantation procedure, payers were denying coverage for resistant depression. In 2006, Cyberonics requested that the NCD for VNS be expanded to include resistant depression. In 2007, an unfavorable NCD was issued, citing the lack of compelling evidence to justify such a move. As of 2013, CMS declined a request from Cyberonics to open a reconsideration of this non-coverage decision, so it remains in place.[18] Even though an NCD only formally applies to Medicare, private payers, while not obligated to follow this lead, often can be influenced by decisions made by CMS. Cyberonics had successfully convinced some private payers to reimburse VNS for resistant depression, but still had to instruct providers to seek reimbursement on a case-by-case basis.

A note on parallel review In 2011, the FDA and CMS established a pilot program for the concurrent review of certain medtech premarket regulatory submissions and national coverage reimbursement determinations. The goal of the program is to promote the development of innovative products and shorten the time it takes to bring these products to patients by reducing the time between FDA marketing approval and Medicare coverage. The pilot program, which companies were invited to participate in voluntarily, does not change the distinct review standards for FDA device approval and CMS coverage determination.[19] However, the two agencies are working together more closely throughout the review and decision process.

One of the companies taking advantage of the pilot program is Exact Sciences, which submitted its non-invasive Cologuard™ diagnostic test for detecting colorectal cancer for parallel review in December 2011. During the review period, Exact Science was positive about its experience. Among the main benefits highlighted by CEO Kevin Conroy was the ability to proactively get input on trial design not just from the FDA but from CMS. "One of the most significant inputs [from CMS] was making sure that the patient population for the **clinical trial** was **powered** sufficiently with Medicare patients," he said, noting that the agency also provided other valuable suggestions.[20] For start-up companies without the resources to run multiple trials, being able to conduct a single study for regulatory and reimbursement offers a substantial advantage. As Conroy put it, "I would go so far as to say that I don't know how from an investment standpoint we could have done this without parallel FDA approval and Medicare coverage and payment."[21] Conroy also indicated that the program could save Exact Sciences up to two years in total review time.[22] In October 2014, Cologuard became the first medical device to receive FDA approval and a final NCD as part of the parallel review process.

On the other hand, parallel review is not without risks. Management from other companies have been nervous about being forced into a NCD by the parallel review process. They have also expressed uncertainty about trying to satisfy two agencies with distinct mandates and evidence requirements at the same time.[23]

Building on the parallel review program, FDA's Center for Devices and Radiologic Health (CDRH) announced another pilot to help streamline the link between regulatory and reimbursement approval called the CDRH Reimbursement Program. Under this effort, a Medical Device Reimbursement Task Force will focus on implementing three new processes: (1) to allow a device company to voluntarily request that one or more identified payers participate in a pre-submission meeting to better inform the sponsor of what evidence is necessary to support both FDA approval/clearance and payer coverage; (2) to modify CDRH's current investigational device exemption checklist, as appropriate, and provide it to CMS upon request to support the Medicare agency in decisions of whether to reimburse studies conducted under an approved IDE; and (3) to work with payers and health technology assessment organizations to determine if CDRH can provide them with summary safety or effectiveness information for a device that might reduce the evidence needs to submit to a payer to support

coverage.[24] While it remained to be seen how this program would evolve, the effort is indicative of a growing interest in increased coordination between regulatory and reimbursement assessments.

Coverage determinations for private payers There are many similarities between the processes used by Medicare carriers and by private payers to evaluate a new technology and reach a coverage determination, but there are also important differences. Private payers typically have their own internal committees (a medical policy or technology assessment committee), consisting of physicians, plan administrators, health economists, and statisticians. These committees evaluate the evidence supporting the clinical necessity of a new procedure, paying special attention to evidence obtained outside academic and well-controlled settings. Precedence-setting coverage decisions by other major payers are also evaluated. For example, in reaching a coverage position for bariatric surgery, Cigna (a major private payer) based its decision on information provided in a CMS coverage decision, technology assessment reports by the Blue Cross Blue Shield (**BCBS**) Technology Evaluation Center (**TEC**) in the US, the National Institute for Health and Care Excellence (**NICE**) in the UK, and a comprehensive review of the literature.[25]

The final outcome of a private payer coverage determination is either full coverage, no coverage, or coverage with restrictions. A significant difference between private payers and Medicare is that private payers may offer multiple plan designs, with certain plans specifically excluding certain procedures (even if they are medically necessary). Again, in Cigna's case, their coverage determination on bariatric surgery does not apply to health plans where such surgery is explicitly excluded.

Payment

As described in chapter 4.3, payments are structured around different systems for reimbursement to hospitals (inpatient and outpatient), Ambulatory Service Centers (ASCs), and physicians.

Hospital payments[26] For *hospital inpatient payments*, the Medicare-Severity Diagnosis-Related Group (**MS-DRG**) code system assigns a single prospectively determined payment amount for all hospital services (except physician charges) associated with a given hospital stay. If a new technology is introduced (and the technology adds expense), the hospital could suffer a financial disadvantage even though the care provided is improved. In this situation, a company has essentially two options: (1) to apply for what is called a new technology add-on payment (NTAP); (2) or to seek a new or revised MS-DRG (see Figure 5.6.2).

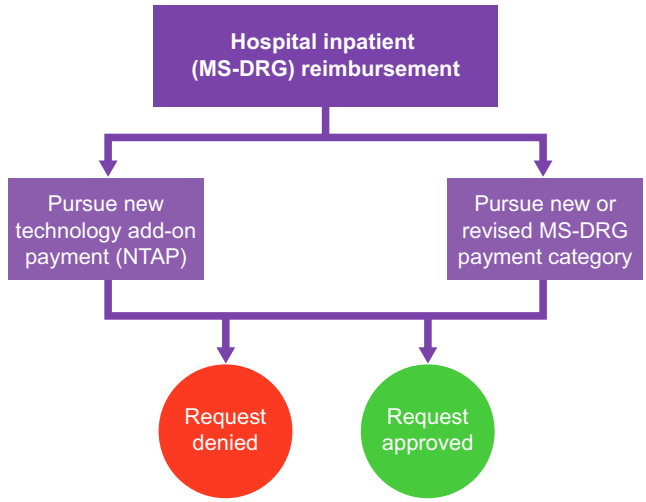

FIGURE 5.6.2
For hospital inpatient payments involving new technologies, companies can apply for new or revised MS-DRG payments or for a new technology add-on payment (NTAP).

In order to qualify for an NTAP, the company must submit an application to CMS providing documentation regarding the new technology to demonstrate that it meets three key criteria: (1) it is an innovative new technology that is not substantially similar to existing technologies; (2) it provides a substantial clinical improvement for Medicare beneficiaries; and (3) it involves high costs and is inadequately paid under the MS-DRG system based on thresholds established by CMS. The add-on payment is issued if CMS determines the technology meets these criteria after reviewing public comments and performing its own review. If the data are convincing, the add-on payment is set at up to 50 percent of the average cost of the new device or 50 percent of the overall incremental costs associated with the new technology to hospitals, whichever is less. The add-on payment lasts for two to three years after FDA approval and

commercialization. By the end of this period, the company should know whether a new DRG will be issued or an existing DRG will be revised to accommodate the new technology. In some cases, obtaining a new technology add-on payment may comprise just one phase of a larger reimbursement strategy. Companies may apply for an add-on payment, but with the expectation that their device will eventually be reimbursed in the outpatient setting, which would require appropriate APC and CPT codes.

The alternate strategy is to continue to initially seek payment under an existing MS-DRG payment category and apply for a new or revised MS-DRG in the future, after hospitals gain experience using the technology. A company might use this approach if the technology does not meet all criteria for new technology add-on payments upon FDA approval, if there is insufficient clinical evidence to demonstrate differentiated value immediately upon FDA approval, or if it is feasible to commercialize within the existing DRG upon FDA approval during the initial stages while additional experience is collected. An example of this approach involved Boston Scientific's efforts to obtain a new DRG for the Guglielmi Detachable Coil (GDC) for catheter-based treatment of brain aneurysms (see Figure 5.6.3). Basically this procedure involves deploying a tightly nested platinum coil within an aneurysm using a special catheter for access. The coil is left behind and it induces a local blood clot to form which, combined with the structural support of the coil, stabilizes the aneurysm and reduces the chance of rupture. The problem that Boston Scientific encountered was that hospitals were losing large amounts of money using the coils because of inadequate MS-DRG payment levels.

FIGURE 5.6.3
An example of a GDC, the Target® Detachable Coil (courtesy of Stryker Neurovascular).

In late 2003, the company presented analysis of Medicare claims data to CMS, showing that hospital costs greatly exceed payments for both coiling and the more invasive surgical procedure of clipping the aneurysm. In its 2004 rulemaking cycle, CMS agreed to the creation of a new DRG for treatment of ruptured aneurysms that doubled average hospital base MS-DRG payments from $17,000 to $34,000 per hospital stay. This successfully expanded access for Medicare beneficiaries to these definitive life-saving treatments.

For hospital *outpatient* payments (but where the care is still delivered within a hospital facility), a company launching a new technology must work within the Ambulatory Payment Classification (**APC**) system. If an existing APC payment category does not provide adequate reimbursement or the descriptors do not match that of the new device, then the company has three choices: (1) seek a pass-through payment; (2) pursue a new technology APC; or (3) seek reclassification of a high-cost new service (typically involving a new CPT code) to a different APC payment category.

The company may apply for a transitional pass-through payment category involving the use of a HCPCS Level II C code to cover the cost of the new device. A pass-through payment is used in the case where there is a new, clinically beneficial, high-cost device being used in an existing procedure (and, therefore, where there are existing APCs that are appropriate). The amount of the pass-through payment is generally calculated as the actual cost for the device, minus the amount already included in the APC payment for the technology that is being replaced. The pass-through provides additional payment for a two- to three-year period while CMS obtains further data on the cost of the technology. For example, in the early 2000s, several companies

brought out a new generation of spinal cord stimulation devices that had rechargeable power sources, providing more and longer lasting power. The ability of these systems to last for much longer intervals between generator replacements resulted in substantial potential cost savings to Medicare over the life of the patient. Based on a concerted educational effort from Boston Scientific, Medtronic, and St. Jude, in 2006 CMS approved pass-through payments on the basis that the existing codes did not "adequately describe" the new technology. The rechargeable neurostimulators from all three companies qualified for new technology payments, and the rechargeable systems captured most of the US market. Once CMS retired the new technology payments for 2008, it decided not to create separate APC payment categories for rechargeables and non-rechargeables. However, despite the cost differential in these two technologies, the significant clinical benefit of the rechargeable systems has driven their continued use as the dominant approach in the US.

The second option is to pursue a new technology APC. A new technology APC will only be issued in the case that the new device also warrants an entirely new procedure that cannot easily be described by an existing APC code or combination of codes. Again in this case, the new technology APC provides a period of time for Medicare to gather actual use data before the APC becomes permanent. Applications for a new technology APC can be submitted at any time during the year and are considered for inclusion in the quarterly updates of the codes. With rare exceptions, applications for transitional pass-through payments and new technology APCs cannot be submitted unless the product has received regulatory clearance/approval. A decision from CMS typically takes several months to obtain.

In some circumstances, especially when a distinct CPT code is established for a new technology involving higher costs, then the manufacturer can convince CMS to reclassify the procedure to a different APC payment category if the cost of the new procedure exceeds two-times the calculated cost of the lowest-costing procedure categorized to that same APC (this is referred to by CMS as the "two-times rule").[27] In such cases, CMS will consider the clinical characteristics and hospital resource costs of the new technology and seek to assign it to the most appropriate APC payment category.

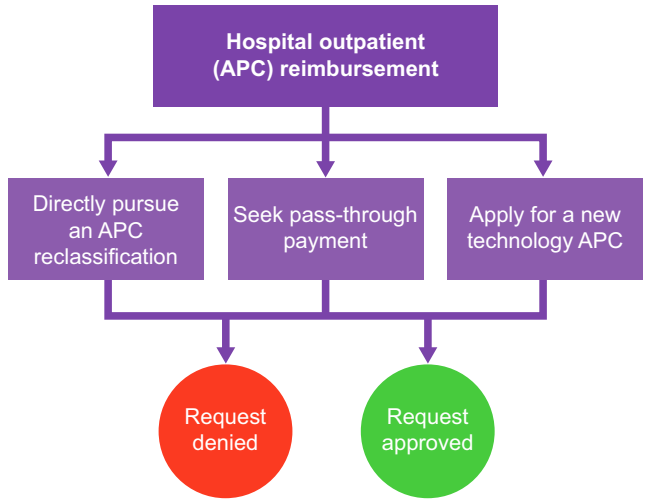

FIGURE 5.6.4
For hospital outpatient payments involving new technologies, companies can seek a pass-through payment or apply for a new technology APC.

Figure 5.6.4 summarizes the APC coding pathways available to medtech companies.

Payments to physicians As noted in chapter 4.3, payments to physicians for procedures under Medicare are based on a determination of Relative Value Units (**RVUs**) associated with each CPT code for inclusion in the national Medicare physician fee schedule. If a company is seeking new or revised codes associated with a new technology, CMS will look for recommendations from the appropriate AMA committees. The AMA Specialty Society Relative Value Scale Update Committee (**RUC**)[28] recommends RVUs for a new code typically based on an established RUC survey of practicing physicians. In some cases, the company may also provide evidence to CMS that demonstrates the time and effort involved in using the device/performing the procedure. This evidence could include economic studies based on surveys or time and motion studies on physician's time, other practice expenses (such as labor and supplies), and malpractice

risk. The RVU recommendations are forwarded by the AMA to CMS, where a final RVU determination is made.

Interestingly, the assignment of payment rates based on RVUs by CMS is budget neutral, meaning that total Medicare funding for all CPT codes remains constant within any given budget year. When a new CPT code is created (or an existing code modified) and a value is assigned to that code, payments made through other CPT codes must be reduced to compensate for the change. Companies must recognize that this creates a disincentive for AMA to approve new codes, especially if they will increase total payment to one specialty at the expense of another. Budget neutrality can raise **stakeholder** issues, especially among specialty societies, as one sees its total payment rates go down while another sees them go up. As a result, these issues need to be identified early and managed proactively.

For CPT codes for diagnostic tests and therapeutics, Medicare establishes a payment level for a new code using one of two approaches. If an existing code is sufficiently similar to the new code in terms of cost, technology, and clinical use, CMS determines the payment amount by "crosswalking" the code – assigning a comparable reimbursement rate to the new code based on its similarities to one or more existing codes. If no comparable code exists, a "gap-filling" method is used to determine a new reimbursement amount. This involves having each local Medicare carrier individually determine an appropriate payment amount for the new code. These recommendations are then shared with CMS, which analyzes the carrier-determined amounts and sets an appropriate payment level for the new code that will be used until the next annual schedule is published. The sponsor will often develop detailed economic studies to support these efforts.

Payment by private payers As with coverage decisions, the fundamentals for setting payment levels are similar for Medicare and private payers, with a few important differences. All payers place a strong emphasis on **evidence-based** medicine, cost, and the demonstration of value. However, Medicare as the largest purchaser of US healthcare services is responsible for publicly disseminating codes and payment rates, so its decisions can serve as the pathfinder, influencing the policies of other payers. For the time being, Medicare still cannot explicitly consider cost as a criterion when evaluating coverage for new technologies (though CMS officials have acknowledged that perceptions of value play an informal role in their coverage decision making). Furthermore, officials from CMS, and to some extent local contractor representatives, may be subject to greater political pressures and lobbying. Private payers are less likely to face such pressures since they have no direct links to elected officials and because their policies and payment schedules are not in the public domain. However, private payers are beholden to their providers, and to the employers and individuals that subscribe to their plans. For innovators and companies, there is often a greater opportunity to develop business relationships with private payers, as public payers (and some non-profit plans, such as Kaiser) restrict their employees' participation in industry-sponsored events and activities. Regardless, whatever contacts and relationships a company has with any payers should be leveraged to help secure appropriate payment levels and help facilitate a smooth reimbursement processes when new codes, coverage, and payment levels are being established.

As enrollment in Medicare Advantage programs and health exchanges grows, many private insurers are expected to become more restrictive in their coverage of category III treatments, which tend to be expensive yet still experimental when it comes to delivering proven value. For example, in the absence of strong cost/benefit data, some private payers have retroactively denied coverage of a costly proton beam therapy for prostate cancer that they previously reimbursed under a category III CPT code.[29]

When processing claims from miscellaneous and temporary codes, private payers have different proprietary formulas for calculating payment levels that are based on contractual negotiations with specific providers including physician practice groups and hospital systems. Each private payer generally uses its own formula to reimburse for billed charges on manually submitted claims. With miscellaneous code claims, payment rates usually amount to a percentage of billed charges for services and/or devices or a flat predetermined allowable. Some

private payers routinely reject or delay all manually submitted claims until they are elevated for special review within the organization. Companies must understand and anticipate this potential outcome in their reimbursement strategies. For devices and procedures that have been recently approved, private payers will typically set their payment at some percentage (usually greater than 100 percent) of Medicare or at a rate that approximates similar procedures and devices.[30] In the hospital, private payers are more likely to pay for each device separately and not lump them into a per diem payment in order to keep hospitals from losing money. Payment rates vary substantially from one private payer to another and depend on heavy negotiation between providers, payers, and the manufacturer.

Building a reimbursement strategy

Whether a company plans to apply for new coding, coverage, and payment or to fit into the existing reimbursement structure, it must develop a reimbursement strategy. A cohesive, proactive reimbursement strategy allows innovators to anticipate the questions payers and other stakeholders will raise about a new technology, identify reimbursement opportunities and obstacles, and integrate necessary evidence requirements into product development and business planning. Given the complexity of the reimbursement landscape, the initiation of a reimbursement strategy must start early in the biodesign innovation process, well before the offering is nearing the market. Any delays can negatively impact product adoption and can threaten the viability of a start-up company.

When developing a reimbursement strategy, the company should take a multidisciplinary approach. At a minimum, the leaders of the regulatory, clinical, marketing, sales, and reimbursement functions must work together to appropriately integrate and sequence key commercialization activities. As indicated, specialized expertise and accumulated experience may also be needed, which is often best obtained through the involvement of a skilled external consultant.

Developing a reimbursement strategy is particularly challenging given the major changes underway in the health economics environments globally. This is especially clear in the US, where passage of the Patient Protection and Affordable Care Act (**ACA**) in 2010 signaled a new era of cost containment pressure. A number of features of the ACA are representative of the general policies and strategies around affordability that are surfacing in many other countries. The act mandated a progressive set of cuts in hospital payments, along with the creation of the Independent Payment Advisory Board (IPAB). The IPAB has the authority to make changes in the Medicare payment rates and program rules without prior approval of Congress. The ACA also created the Patient Centered Outcomes Research Institute (PCORI), which is charged, in part, with evaluating the comparative effectiveness of new innovations, such as devices. The ACA authorized CMS to experiment with different mechanisms for containing costs, such as **bundled payments** for certain types of care episodes. A new Shared Savings Program was also created to facilitate coordination among providers, in part through the formation of Accountable Care Organizations (**ACOs**). The Act further expanded the implementation of "**gainsharing**" mechanisms, through which physicians and hospitals can receive payments linked to cost savings achieved in the delivery of healthcare. (Programs such as gainsharing can influence how innovators choose to price their products as discussed in 5.7 Marketing and Stakeholder Strategy.)

Given the scope and complexity of these changes, innovators and companies have a major challenge in understanding which policy changes have already been implemented, which are still coming, and what the timetable will be for the remaining roll-out. The situation is complicated even further by the intense political nature of healthcare reform, with uncertainty whether major portions of the law will be revoked or changed. Despite this fairly massive uncertainty, however, the general direction of economic reform of healthcare in the US and other global markets is clear: decisions about reimbursement will be driven by assessment of value, with an overall goal of reducing healthcare expenditures. The net result is that, more than ever, reimbursement strategy is becoming a key driver of success for the introduction of a new technology.

A reimbursement strategy certainly cannot account for every possible scenario that might impact the payment

landscape. The point is that innovators should take a forward-looking position when developing their strategy and make a best effort to anticipate what changes are most likely to occur. With this framing in mind, an effective reimbursement strategy addresses a combination of decisions and activities, including those related to competitors/proxies, pricing, payer segmentation, clinical trial design, payer **value propositions**, and disseminating critical information to marshal support from physician and patient advocacy groups as well as a potential **payer advisory board**. All of these topics are touched on in the sections that follow.

Competitors and proxies

Identifying competing products and clinical trials underway is an important early step in devising a reimbursement strategy. If two companies are commercializing similar products, understanding the competitor's approach to gaining reimbursement can prevent conflicting or contradictory reimbursement efforts that could jeopardize both parties.

If the technology is completely new, the analysis can be structured around a proxy device – that is, a technology that is already on the market and has relevant similarities to the new product. Proxy devices should have a related function within the same or similar specialty, and should be used by the same type of provider in a comparable site of care. Other comparators to consider include the disease state or mechanism of action.

In most countries, including the US, reimbursement is typically attained for a type of technology, and is not manufacturer-specific. Therefore, a second-to-market company can potentially benefit from understanding the strategy of the first market entrant and save significant resources if the strategy is amenable to its product. Depending on the timing of a competitor's launch, companies may consider this situation similar to one in which they seek coverage under existing codes. However, just because a competitor attains reimbursement first, there is no guarantee that the follow-on technologies will also be reimbursed. Clinicaltrials.gov remains the best public source of clinical trial information, although reimbursement information is typically not provided.

Pricing

Pricing decisions are an essential component of a company's reimbursement strategy. As described in 5.7 Marketing and Stakeholder Strategy, the company will need to set a price that makes the device affordable at the reimbursement levels it expects to secure from payers. To determine the appropriate price, many companies perform what is known as demand curve analysis or value-based pricing. This exercise involves assessing the price sensitivity of providers and key payers to determine the range within which the company can secure adequate reimbursement, which in turn determines how to realistically price its product. The Genomic Health example provided in chapter 5.7 demonstrates how value-based pricing works.

Pricing assumptions directly impact cost models and can exert a substantial influence (positive or negative) on reimbursement. For example, if a new technology substantially improves clinical outcomes but the company sets pricing at a level that does not meet new technology add-on payment cost thresholds, then the technology may not qualify for premium reimbursement. Further, if the company lowers prices before reimbursement rates have been formalized, the final reimbursement may account for the lower price and lead to a reimbursement level that does not cover the cost of the procedure and device, therefore limiting adoption. In contrast, if the price is set at a level that significantly increases the budget impact to the payer without corresponding clinical or economic value, then the payer may respond with negative reimbursement decisions that limit adoption.

Outside the US, pricing is sometimes determined using an approach called **reference pricing** (i.e., setting a price relative to what is charged in another market or geography). When reference pricing is in place, the sequence in which a company releases a product in different markets can be important – it should first be released in countries where a higher price can be commanded.

Payer segmentation

Because early-stage start-ups have limited resources, they typically need to prioritize which payers to approach. At least one year before launch, a company should initiate efforts to segment payers. Some payers will allow

immediate use of an approved device (in accordance with product label) at launch, while others will mandate a 6- to 12-month waiting period. Within these more restrictive plans, exceptions may be allowed to varying degrees. Some payers will permit device use after an appeal is made by a physician or physician organization and found to be justified. Often, these waiting periods culminate in an intensive review of the technology (i.e., technology assessment), during which clinical and economic data is scrutinized and the new technology is compared holistically to others in its class or therapeutic area. The outcome of this analysis leads to a final decision about the reimbursement status of the device within that plan. Some payers will wait and follow the lead of assessments performed by TEC or other such committees, while other payers will be more likely to approve more quickly in a manner consistent with the label.

Information about how different payers respond to new technologies (based on primary payer research) can generally be purchased from a reimbursement consulting firm and then used to perform a preliminary payer segmentation. Common criteria used to segment payers include their openness to new technology and the stringency of their review process.

Whenever possible, the number of patients covered by payers in each segments should be estimated to help the company more efficiently allocate the time and focus it will devote to each payer at launch. In general, a small device start-up should follow the 80/20 rule – targeting the top 20 percent of payers that cover 80 percent of patients. At a minimum, companies working in the US should include Medicare and one to three prominent private payers in their initial reimbursement strategy (for the private payers, identify the ones most likely to adopt/cover the new technology).

Design of clinical trials

As mentioned in 5.3 Clinical Strategy, considerations related to reimbursement have an increasingly important influence on the design of clinical trials. Just as company representatives should meet with the FDA or other regulatory agencies early in the biodesign innovation process to understand what evidence will be required to gain regulatory approval, they should do the same with payers to understand what data will be most likely to convince them of a new technology's value proposition and lead to reimbursement. In particular, payer feedback should be solicited on reimbursement-related endpoints for clinical trials. These endpoints, which are often incremental to endpoints included for regulatory purposes, can be expensive to generate. They can also introduce significant risk, as failure to show a positive effect will work against efforts to support reimbursement.

Gaining feedback from payers will help to determine that the resulting data will have a positive impact. Endpoints should be selected based on the likelihood of addressing important payer concerns (see Table 5.6.2 for a list of concerns to be addressed), for their probability of success, and their ability to support simple, clear value messages that resonate with payers, physicians, patients, and the public.

Outcomes data that address economic value are critical to reimbursement if a company's goal is to market the product outside of the US, particularly in countries with nationalized payer systems such as the United Kingdom, France, or

Table 5.6.2 Evidence to support reimbursement must explicitly be collected as part of a clinical strategy.

Concerns to be addressed by reimbursement-related clinical trial endpoints
What are future significant expenses for patients with this disease or condition?
What expenses could payers avoid as a result of funding the technology?
What inefficiencies exist with the current **standard of care**, and how does the new device address this?
What unacceptable risks are inherent in current treatment standards, and how does the device minimize these?
Do the outcomes that the device will deliver provide patients with a highly compelling reason to seek treatment?
Is the target patient population young, or of working age, and will the device affect their productivity or ability to work?

Australia. It is also becoming increasingly important for establishing private payer reimbursement in the United States. Data from clinical studies serve as direct inputs into the creation of the economic evidence needed to support a strong payer value proposition.

Payer value propositions and building economic evidence

A significant milestone on the path to commercialization is a company's development of one or more value propositions for its offering (as described in more detail in 5.7 Marketing and Stakeholder Strategy). Metrics for demonstrating value can vary widely, but typically seek to express improved outcomes resulting from a product's use relative to the cost of treatment. Such outcomes may be assessed for individuals, populations, institutions, or society as a whole; and may cover clinical, economic, social, or other measurable effects. When it comes to reimbursement, public and private **third-party payers** and technology assessment panels insist that products are supported by strong value propositions. But, increasingly, such stakeholders want to review data that support those value statements.

Value propositions should be clear and simple, avoiding tenuous projections based on intermediate markers of efficacy. They should also be based on data from **randomized controlled clinical trials** and/or well-defined value models, whenever possible. Using data collected from a patient population and provider type that resembles that of the targeted health plan is also important for maximizing a company's likelihood of success. The Working Example focused on implantable cardioverter defibrillators illustrates a strong, data-driven value proposition.

As mentioned, CMS excludes any explicit cost and cost-effectiveness evidence in its coverage decisions in the US (at least for now). On the other hand, private US payers, such as Blue Cross Blue Shield and Aetna, are increasingly looking at explicit measures of value (health improvement as a function of cost) in assessing the

Working Example

Sample value proposition for the cost of treatment with an implantable cardioverter defibrillator[30]

Research shows that implantable cardioverter defibrillators (ICDs) provide an invaluable form of "life insurance" for people most at risk, preventing sudden cardiac arrest (SCA) death 98 percent of the time. Evidence-based medicine has demonstrated that ICDs significantly reduce death among Americans at highest risk:

- 31 percent reduction in death among SCA survivors from a second event.
- 31 percent reduction in death among post-heart attack sufferers.

Despite these statistics, ICDs have been thought to be underutilized, at least from the standpoint of their potential to reduce sudden cardiac arrest and the economic consequences of this deadly condition.

- Fewer than 20 percent of indicated patients receive the benefits of an ICD despite being at high risk for sudden death.
- Although SCA is responsible for more deaths than breast cancer, lung cancer, stroke and HIV/AIDS combined, spending on SCA prevention is modest when compared to other diseases (AIDS = $19.5 billion; stroke = $6 billion; lung cancer = $1.6 billion; breast cancer = $0.8 billion; SCA = $2.4 billion, including drug and device therapy).

The value of ICDs outweighs their cost to the system:

- An ICD costs approximately $25,000 (including implant costs), which equates to less than $10 per day over the average life of a device (four to five years).
- The cost per day of ICD protection has decreased by nearly 90 percent over the last 10 years from more than $90 in 1990 to less than $10 more than a decade later (equivalent to the cost of optimal medical therapy for these same patients).
- ICD Medicare expenditures are significantly less than for other cardiovascular procedures. In 2002, Medicare reimbursed $1.2 billion for ICD procedures versus $6.4 billion for stent implants and $7.8 billion for bypass surgery.
- The cost of ICD therapy per year is less than 0.2 percent of projected Medicare spending over the next 10 years.

suitability for reimbursement (see online Appendix 5.6.1 for an overview of the Blue Cross Blue Shield Technology Evaluation Center). Outside of the US, health economic data is often required as part of a health technology assessment prior to obtaining reimbursement. For example, in most advanced European nations and many countries in Asia, new devices undergo technology assessment before they are approved for use in nationalized healthcare systems.

Payer value propositions can be significantly enhanced by the inclusion of information from economic models that demonstrate the relation between the health improvement gained and the corresponding costs. Models can be especially helpful for companies seeking to develop economic evidence prior to launch (when limited clinical and cost information is available) in that they allow the company to project outcomes and related costs over time. Which type of model to deploy will depend on the nature of the data available, the purpose of the analysis, and the target country and agency. Companies typically should work with health economists and/or reimbursement experts to help in model development to ensure they meet payer and administrator requirements. Some of the most widely used types of health-economic value models are listed below (see online Appendix 5.6.2 for examples that correspond to each one):

- **Cost analysis** – Cost analysis can be the strongest and most persuasive type of modeling to payers and administrators. It compares the money spent on competing treatments over time from a payer, provider, and/or societal perspective. If a new treatment that is safe and effective (superior or at least non-inferior) to alternative treatments can be shown to produce overall costs savings, then this may be sufficient by itself to warrant positive reimbursement decisions without the need to perform more extensive modeling.
- **Cost-effectiveness model** – Cost-effectiveness analyses evaluate the total incremental cost of the intervention per incremental unit of net health benefit experienced by the patient. In cost-effectiveness analyses, health gains can be measured in a variety of "natural health unit" measures (e.g., treatment successes, cures, lives saved, blood pressure levels, repeat revascularization procedures avoided).
- **Cost-utility analysis** – Cost-utility modeling is a special form of cost-effectiveness analysis where health gains are measured using a generic Quality Adjusted Life Years (**QALY**) construct designed by economists to reflect both quality of life and years lived. Quality of life indexes are multiplied by the number of years gained. Incremental cost-effectiveness is then expressed as a ratio of the incremental costs over the incremental QALYs gained for one treatment when compared to another. This model is often used by national health systems as the standard for evaluating reimbursement outside the US. Commonly used thresholds for determining what constitutes acceptable economic "value for money" in the US are $50,000 per QALY gained or $100,000 per QALY gained when compared to the best available treatment.
- **Budget impact models** – Budget impact models look at the cost and treatable population from the perspective of a particular purchaser of services (e.g., government healthcare program, private health plan, hospital system), as well as the expected annual cost to the plan of covering the device based on the anticipated level of adoption and pricing. The results are normally evaluated in terms of annual cost or per-member, per-month costs. Often, a cost-effectiveness model and a budget impact model will be combined.

When developing a model, companies may produce multiple variations to address the unique interests and requirements of specific stakeholders (e.g., medical specialty societies, government and private third-party payers, hospital systems, ACOs). When data are uncertain or cover a wide range of potential outcomes, they can also experiment with sensitivity analysis to better understand the strength and meaning of varied findings. The approach here is to define a "base case" and then make adjustments to the model's key input assumptions to test the robustness of the base case findings.

Of note, innovators should be sensitive to any price increases or competitor discounts included with a model, as they can "live on forever" once it is distributed, potentially working against the product in the future. The value propositions derived from a model will become important tools to help the company build advocacy and to assist the company's advocates in favorably affecting coverage and reimbursement policies.

The story about a cost-effectiveness study for a new treatment for obstructive sleep apnea illustrates the complexity of creating a value model, but also highlights the benefits that can be realized from the effort.

FROM THE FIELD — WING TECH INC.

Early-stage value modeling to support reimbursement

Early-stage technologies often lack the long-term clinical data or peer-reviewed publications that would ideally form the basis for reimbursement decisions. In many cases, the benefits and cost savings resulting from the use of new diagnostic or therapeutic devices do not become measurable until years after the intervention. In the absence of such data, health-economic modeling can provide quantitative projections of the expected long-term outcomes and costs of new interventions. Accordingly, value modeling has become an important tool for informing the reimbursement-related decisions of both government agencies and private payers. Additionally, the early-stage assessments required to develop such models can also benefit innovators by helping them develop a solid understanding of key value drivers and metrics. In the words of Jan Pietzsch, CEO of Wing Tech Inc., a consultancy specializing in early-stage value modeling, "Health-economic modeling enables innovators to make quantitative, evidence-based statements about a wide range of potential benefits associated with a new technology."[32]

In a recent example of such a study, Wing Tech collaborated with principal investigator John Linehan of Northwestern University to create a health–economic model for evaluating diagnostic and treatment strategies for obstructive sleep apnea (OSA), a chronic condition in which the patient's upper airway collapses repeatedly during sleep. OSA is significantly underdiagnosed and undertreated, and it is associated with numerous adverse consequences, including cardiovascular disease, depression, diabetes, obesity, and stroke, as well as excessive daytime sleepiness that can lead to motor vehicle collisions (MVCs).

The study, "Assessing the Impact of Medical Technology in the Diagnosis and Treatment of Obstructive Sleep Apnea," was supported by a grant from the Institute for Health Technology Studies (InHealth). It was designed to quantify the value contribution of existing medical technologies used in diagnosing and treating OSA and, specifically, to develop an analytical framework for evaluating various diagnostic strategies. An additional objective was the development of an analytical framework for future evaluation of any new types of OSA diagnostic or therapeutic interventions.

The current gold **standard treatment** for OSA is continuous positive airway pressure (CPAP). Physicians use one of three common diagnostic strategies to determine whether a patient has OSA and whether CPAP treatment is indicated:

- Full-night polysomnography (FN-PSG) – The patient spends two full nights in a sleep lab; one for assessment and the other to titrate the CPAP therapy if the diagnosis is positive for OSA.
- Split-night polysomnography (SN-PSG) – The patient spends one night in the sleep lab for both assessment and titration.
- Unattended portable home monitoring (UPHM) – The patient is evaluated with a portable home monitor, followed by unattended CPAP autotitration.

These diagnostics differ in their sensitivity and specificity, as well as their cost to the healthcare system. To determine which method was most cost-effective, the researchers constructed a two-part model for comparing the end-to-end costs and effectiveness associated with each diagnostic strategy when evaluated in conjunction with subsequent CPAP therapy over the course of the patient's lifetime.

They began by identifying published, large-scale cohort studies and other clinical evidence in order to define the diagnostic and therapeutic pathways currently in use and to establish the relative effects of each pathway on health outcomes related to OSA. According to Pietzsch, one of the most significant challenges for model development involves whether published information is available on which to base long-term projections. "When there are established models and long-term epidemiological studies, researchers usually have the evidence they need to define the risk equations and populate the model," he explained. "But where that information is not available, creating a meaningful model is much more difficult."

Existing studies helped the Wing Tech research team understand pertinent elements of the current standard of care, for example, how existing technologies perform, how performance is measured clinically, and the costs of technology-related interventions and clinical events. The team's research also enabled it to quantify and assess the importance of societal outcomes related to OSA, including daytime sleepiness leading to motor vehicle collisions. Measuring non-clinical outcomes such as quality of life, return to work, independence, and productivity can often play an important role in deepening payer understanding about the value of a technology or procedure. When incorporated into a health–economic model, the costs and savings attributable to societal outcomes are readily apparent. Whether or not innovators ultimately go on to develop a health–economic model, Pietzsch explained, this investigational step is essential because "It allows you to identify and pinpoint the characteristics of a technology that really matter – and how you can use this information to make a value statement about that technology."

For the second part of the OSA study, the Wing Tech team built on its analysis of the existing literature to quantify the benefits and cost-effectiveness of CPAP diagnosis and treatment in patients diagnosed with OSA. The team took as its base-case population a hypothetical cohort of 50-year-old male patients with a 50 percent prevalence of moderate-to-severe OSA.[33] The team's analysis focused on adverse cardiovascular events, motor vehicle collisions, and stroke – three areas of high risk for OSA patients – and projected CPAP-related reductions in the average number of such events over a 10-year period, and over a patient's expected lifetime.

In this analysis, the team developed two complementary mathematical models. The first was a multifaceted decision-tree model of current diagnostic pathways (see Figure 5.6.5), which the researchers populated with respective test performance, diagnostic outcomes, and costs as described in the literature. This model enabled the researchers to classify patients according to a starting diagnosis and disease state, and to assess patient outcomes along the pathways during the study timeframes.

The second was a Markov (state transition) model. This type of model is commonly used to illustrate the expected disease progression of a hypothetical cohort through a set of mutually exclusive and collectively exhaustive health states. In the case of the OSA study, health states included the clinically and economically relevant disease states of hypertension; myocardial infarction (MI) and post-MI; and stroke and post-stroke (see Figure 5.6.6). This second model allowed the team to compute the estimated disease progression, costs and outcomes over the patient's lifetime, using the initial results of the diagnostic pathways model as inputs.

The results of the OSA study quantified the health benefits of diagnosis followed by CPAP therapy, demonstrated the cost savings of therapy as a result of reduced illness and death, and showed that the most expensive method of diagnosis under study was actually the most cost-effective of the strategies. Projected over a

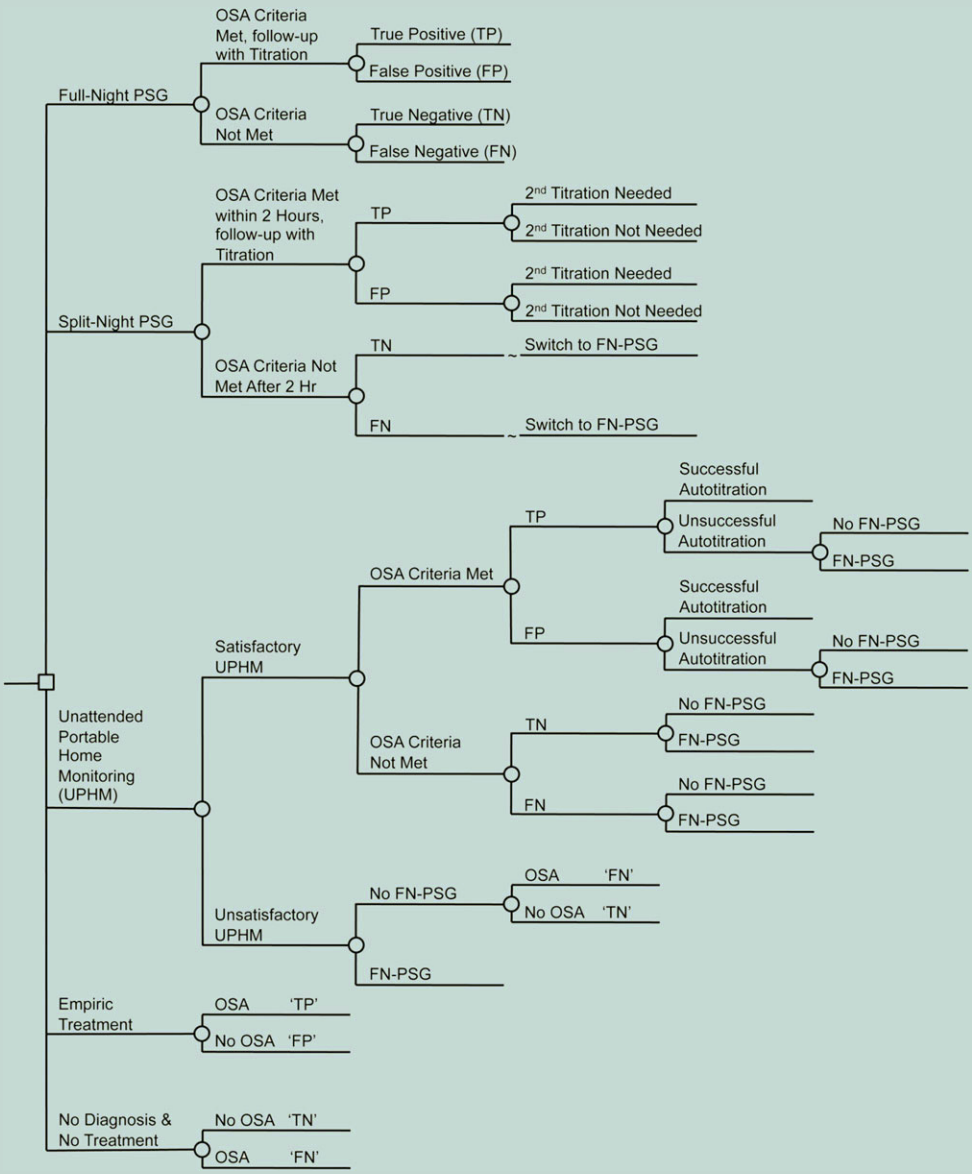

FIGURE 5.6.5
Simplified illustration of the decision-tree structure (diagnosis and titration only). The small square represents the decision to implement a strategy of using a specific diagnostic technology. Circles represent chance events. TN: True Negative; FN: False Negative; TP: True Positive; FP: False Positive (courtesy of Wing Tech Inc.).

10-year period, the team's analysis demonstrated that CPAP therapy can be expected to reduce the risk of motor vehicle collisions by 52 percent, the expected number of heart attacks by 49 percent, and the risk of stroke by 31 percent.[34] When projected over a lifetime, the predicted risk reductions were less pronounced – a result of CPAP-related increases in life expectancy – but they were still significant.[35]

For data projected over a lifetime, the research team quantified the cost savings associated with the reductions in **morbidity** and mortality for OSA patients who received CPAP therapy. The incremental cost-effectiveness ratio (ICER) of CPAP therapy compared to no treatment was $24,222 per life-year gained, and $15,915 per quality-adjusted life-year (QALY) gained – well below the commonly recognized willingness-to-pay threshold of $50,000–$100,000 per QALY.

Because full-night polysomnography had the greatest diagnostic accuracy, its use significantly reduced the rate of false-positive findings, which meant that, in the long run, it cost less and provided greater health benefits than

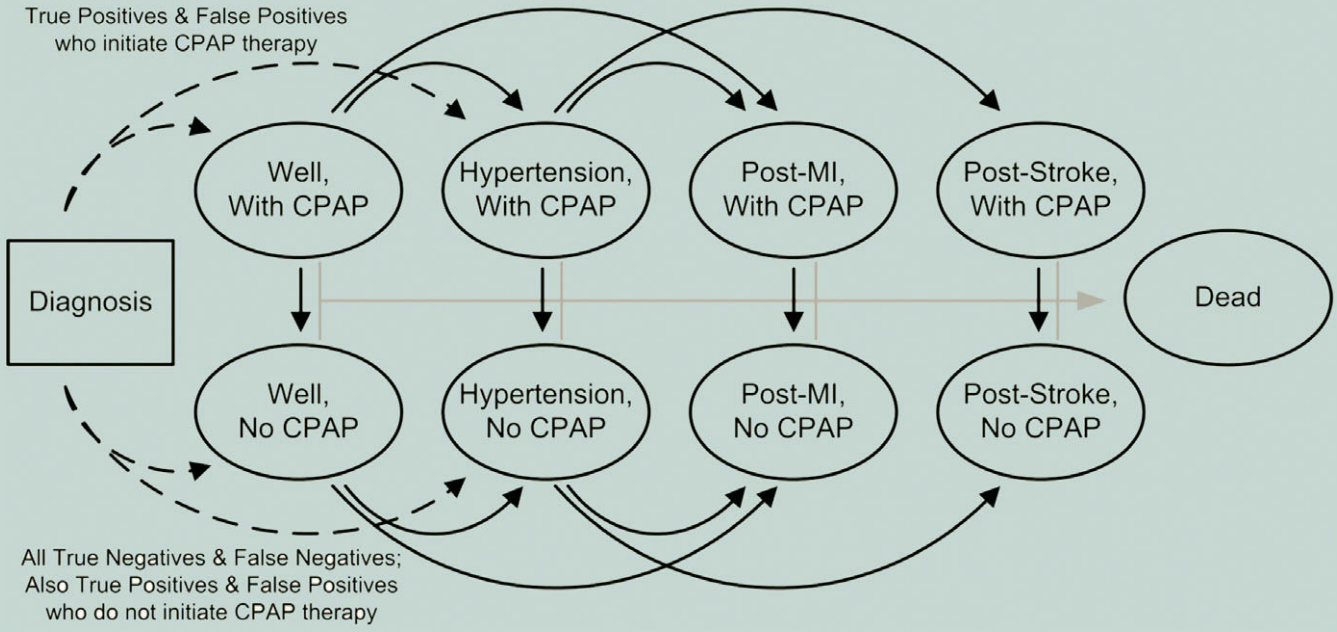

FIGURE 5.6.6

Schematic of the Markov component of the model. Patients are initially distributed based on their diagnosis. Each month, patients can either die, stay in the existing state, or transition into one of the other health states as indicated by the arrows (courtesy of Wing Tech Inc.).

any other approach to diagnosis – even though it was the most expensive approach in terms of upfront costs. At the same time, the study showed that in cases where lab-based diagnosis is unavailable, portable home monitoring can be a viable and cost-effective alternative diagnostic solution. At a time when payers were hesitant to cover or provide reimbursement for portable home monitoring to diagnose OSA, Pietzsch observed that the combination of findings from this study "provided useful insights to guide decision making about coverage and reimbursement of the various diagnostic strategies."

To make the model relevant for evaluating new OSA-related technologies and therapies, the researchers would first incorporate new clinical and economic evidence gathered by innovators during testing or clinical trials of the new technology or procedure, such as therapy compliance or the rates of false-negative and false-positive diagnoses. Using these inputs in the OSA model, the impact of the innovation on relevant health and societal outcomes and costs can be projected.

Next, findings generated by the new model could be used to estimate the relative clinical and economic benefit of the new technology compared to existing technologies.

Reflecting on the value of health-economic modeling, Linehan noted that, "Particularly in complex healthcare scenarios such as those surrounding OSA, where societal implications can be as important as clinical outcomes, it is important to use all available evidence to support decision making. Decision-analytic models like the one completed in this study can help policymakers to understand the clinical and health-economic value of clinical strategies that employ diagnostic and therapeutic technologies." In the absence of data from clinical trials or actual use, healthcare decision makers have come to recognize the value of forecasts developed through health-economic models. "It is increasingly common for innovators to conduct a short-term clinical trial in which some basic evidence is collected and then create a model for projecting the longer-term health-economic profile," Pietzsch added.

That said, developing health-economic models and studies often involves considerable time and cost, so they may not be practical for all new technologies or procedures. According to Pietzsch, modeling is especially well suited for studying innovations whose benefits are realized over an extended period of time. "When the effects of technologies and procedures are fully apparent within the study and follow-up periods of a clinical trial, it's possible to formulate a solid argument for adoption and reimbursement based on that information plus some evidence about costs. However, for technologies that have longer-term effects, projections or models can help innovators and payers to understand and appreciate the longer-term implications that define the product's value proposition," he said.

Even if innovators choose not to develop a formal model, Pietzsch suggested, at the very least they should establish a frame of reference by mapping out the clinical consequences and costs of the standard of care, and considering what evidence could support a distinguishing assessment of the clinical benefits and cost effects of the new therapy. "Ultimately, innovators need to be prepared to make qualified and meaningful statements about the expected cost-effectiveness of their new technologies," he concluded.

As the OSA example highlights, considering whether a value model might be useful in driving reimbursement and adoption can help innovators think critically about the data that is needed to support a compelling payer value proposition. In particular, it helps uncover unknown factors that might make it difficult to formulate a meaningful value statement. As Pietzsch described, "Understanding what information is missing can lead innovators to de-risk their technologies early and in a highly-focused way because they know the key uncertainties that need to be resolved."

Another benefit is that value models can help innovators determine which individuals are most likely to benefit from the treatment. By incorporating data relating to a variety of patient populations with differing characteristics, they can be useful in designing subsequent clinical trials and deciding on inclusion criteria. Additionally, analysis of the dynamics and effects of treatment can help innovators select appropriate endpoints to be studied and ensure that the right clinical evidence is collected for demonstrating the value of the procedure to payers. Study data may also help innovators to devise a rollout strategy for the technology.

Disseminating economic evidence

Providing well-organized economic evidence to important decision makers and other stakeholders is a critically important part of any reimbursement strategy. Documentation is frequently distributed by the company and its sponsor in the form of a **reimbursement dossier** (also sometimes referred to as a "global value dossier") to support the product through this process. A reimbursement dossier can serve as the official source for all key information about the product, including some or all of the topics outlined in Table 5.6.3.

Because the content of a dossier is comprehensive, it is like a roadmap when presenting to payers. Compilation of the data and messages needed to complete the dossier is a lengthy and intensive process that requires the support of specialty medical personnel, as well as experts in cost-modeling, marketing, and managed care. Work should begin up to two years prior to approval to ensure completion before launch. Planning for dossier development should begin even earlier; during **concept** screening the company starts to anticipate the evidence that will be necessary to gain reimbursement. Ideally, a dossier is distributed to payers just after final labeling becomes available from the FDA (or other relevant regulatory body).

For reimbursement decisions outside the US, the dossier (adapted to fit individual country standards) will be essential, as deliberative meetings with industry personnel and advocates are less likely to occur, and a well-documented **need** for the technology will be essential.

Table 5.6.3 A reimbursement dossier can be an important communication vehicle for information related to a company's reimbursement strategy.

Topic	Description
Basic product information	Materials and mechanism of action, indications and product labeling, product cost, associated codes, access, and distribution.
Place of product in therapy	Epidemiology of disease, approaches to treatment, alternative treatment options, product positioning, and expected outcomes of the technology.
Key clinical and economic studies	Treatment populations, number of people studied, study designs, clinical and economic outcomes measured.
Summary of results	All published and unpublished results of clinical studies.
Disease management strategies	Overview of ancillary or disease care management to accompany treatment.
Outcomes studies and economic evaluation supporting data	Results of outcome and economic studies.
Modeling report	Information on cost model(s) and assumptions, results of inputs, parameter estimates, applicable time-horizon and discounting.
Product value and overall cost	Overall justification of cost given data presented.
References	To support all data provided.

Beyond developing and distributing the reimbursement dossier, it is important for the company to publish economic results and key value propositions in peer-reviewed clinical journals and journals targeted to the managed care audience. Often, health economists and/or reimbursement consultants will co-develop and coauthor an article with a physician key opinion leader who was included in the clinical trial. There should also be a publication plan for favorable outcome endpoints from clinical trials as soon as they become available, not just in the clinical journals but in managed care journals as well. For devices that are likely to broaden their indications and usage over time, it is important to plan studies and publications well in advance to support such an expansion.

In order to gain maximum reach with its messages, a company should submit data as abstracts at specialty society and managed care meetings to be published and presented by a KOL. Abstracts and oral presentations are good vehicles for generating positive press, and effective coordination can provide new coverage of the product at the industry, local, or national levels. Scientific symposia at national managed care meetings can be sponsored by the manufacturer to showcase clinical and economic data to payers. At some meetings, an exhibit booth is also available for sponsorship.

Physician and patient advocacy

Physician advocacy is central to reimbursement success. Developing unique value propositions that specifically focus on physician reimbursement can be useful to get physicians on board with a new technology (see chapter 5.7). Managed care plans are motivated to retain good physicians and, provided the costs are not prohibitive, do not like to deny therapeutic resources that the doctors feel are integral to providing good care. Physicians often see new devices as important innovations that fill an unmet need or have the potential to increase safety and efficiency.

Specialty societies are invested in guiding their profession, helping physicians provide innovative care, gain prominence, and operate financially robust practices. Not only will physician specialty groups be called on to sponsor the creation of new reimbursement codes, but they have the ability to generate positive pressure and influence health plan decision making. Conversely, societies can become powerful enemies in the reimbursement process if the new technology threatens a

long-established practice (and/or the revenue stream) for a particular group of physicians (see Stage 6 of the Acclarent case study). In building a case for reimbursement, it can be essential to develop and maintain personal and professional relationships with the physician members and officers of the relevant specialty societies.

Depending on the disease or condition in question, patient advocacy groups can also be mobilized to support the case for reimbursement, particularly if the benefits of the technology are easy to understand and promise significant improvements in quality of life. Patient advocacy groups should be engaged early in the reimbursement process. Strong value propositions are important both to attract patients and to harmonize their advocacy message as they network with others who may have an interest in the new technology. Patient advocacy groups can have an impact on payers through public relations campaigns and direct appeals to health plans. The ability to demonstrate enhanced patient outcomes related to workplace productivity is highly valued by health plans (because they can use this information in their marketing messages to retain and acquire the employers that make up their customer base). Furthermore, private health plans do not want to risk losing members by denying patients access to a technology that is perceived as useful. The threat of negative publicity is a major consideration for payers when deciding whether or not to cover a particular technology.

Payer advisory boards

Establishing a **payer advisory board** (that consists of KOLs and medical directors from select payers in the target payer segment) provides an important way for a company to build relationships with and create awareness and support for the device among payers. Initially, smaller advisory board meetings can be held in order to gather feedback on the product. They can also be used to evaluate the technology's chances for reimbursement success at different prices and/or to validate clinical and economic endpoints. As clinical trials progress and the regulatory submission process begins, the nature of information gathered at an advisory board meeting will shift to the viability of reimbursement given possible outcomes, coding recommendations, and forward-looking strategies with payers. Just before launch, payers will be able to provide timely information about claims processing, payment amounts, patient prior authorization requirements, provider and facility requirements, and timing of technology assessments. They can also provide the company with feedback on the **financial models**, dossiers, marketing materials, and reimbursement literature that it has developed.

Successful advisory boards can be national, but are more often regional in nature. Their meetings are sometimes planned to coincide with managed care society conventions to make participation easy for payers. They can be held in person or through conference calls and/or webcasts. The typical agenda for a meeting begins with a physician KOL (who is an advocate for the technology and has participated in product testing or a clinical trial) presenting epidemiology data, evidence of an unmet need, clinical data, clinical vignettes, and proposed use to the other members of the payer advisory board. Ideally, this physician will have a strong reputation within the clinical community, good relationships with relevant specialty societies and payers, and will have presented to such an audience successfully in the past. A representative from the company (senior executive, reimbursement staff or clinical-regulatory leader) might next present product positioning, patient population information, progress with FDA, the timeline for launch, proposed code use, value-added services, and the distribution plan. This may also be a good time to vet sections of the product dossier or the validity of economic models. In the event that there is a discrepancy between payer and patient understanding of unmet need, a patient advocate from the clinical trials can be a helpful addition to the meeting. Because an honorarium is typically offered to attendees, not all payer representatives will be allowed to participate in off-site industry-sponsored advisory boards (some health plans limit such employee involvement to avoid conflicts of interest).

The case study on VNUS Medical provides an interesting example of the critical role that reimbursement strategy played for a company that initially thought it could work within established Medicare coding, coverage, and payment policies but ultimately ended up with a different reimbursement pathway.

FROM THE FIELD VNUS MEDICAL

Navigating the twists and turns of reimbursement strategy

Brian Farley was the first employee of VNUS Medical Technologies, Inc., a company that developed a minimally invasive alternative to vein stripping surgery to treat symptomatic venous reflux disease. This progressive condition occurs when faulty valves in the veins of the legs allow blood to flow backwards and pool, causing leg pain, swelling, skin ulcers, and varicose veins. The VNUS Closure™ technology, also known as radiofrequency thermal ablation, involves threading a catheter into the affected vein and using radiofrequency energy to heat the vein wall. The heat causes collagen in the wall to shrink, collapsing and then sealing the vein. As compared to conventional vein stripping, the standard of care at the time, radiofrequency thermal ablation is equally effective at relieving venous reflux, but causes significantly less post-operative pain and bruising and facilitates a faster return to normal activities. The VNUS Closure technology was cleared by the FDA via the **510(k)** pathway based, in part, on data from a 40-person clinical trial (see Figure 5.6.7).

FIGURE 5.6.7
The VNUS radiofrequency ablation catheter and radiofrequency generator (courtesy of Brian Farley).

In preparing its commercialization strategy for the US market, the VNUS team conducted an early investigation of the reimbursement landscape. “Doctors interested in using the product would be able to utilize an existing CPT code for Medicare reimbursement,” described Farley, who was President and CEO of the company at the time. CPT code 37204, which covered “trans-catheter occlusion, any method,” was not originally designed with radiofrequency thermal ablation in mind, but it provided “a best fit, which according to the CPT coding books, was the guideline for choosing a CPT code,” Farley summarized. VNUS initially advised physicians to check with the insurers, many of whom supported the use of this code in conjunction with a corresponding radiologic imaging code, CPT 75894 (a supervision and interpretation or S&I code), since the doctor would be using non-invasive ultrasound imaging to guide the catheter placement in the leg vein. In combination, the payments associated with the two codes adequately covered the costs of the device and the physician’s time, which boded well for the early adoption of the technology.

Another positive indication came from the Society of Vascular Surgeons, the primary professional society involved in vein stripping. “The Society passively supported the use of the 37204 code for the new procedure by not suggesting that a new code was needed or intervening for a number of years,” Farley recalled.

With regard to establishing coverage from Medicare and private payers, the VNUS team anticipated that this could be a varied and unpredictable undertaking. For example, some private insurers agreed that the treatment was a medical necessity, but did not believe that the description for CPT code 37204 provided a good match. As a result, they asked providers to bill for reimbursement using a miscellaneous CPT code, 37799, designed to cover any vascular procedure without an existing descriptor. In order to realize a reasonable level of reimbursement under a miscellaneous code, doctors

had to submit highly detailed operative notes, including a step-by-step account of the activities involved in the procedure and a comprehensive list of all equipment and supplies used in delivering treatment. Although the process was not difficult, physicians disliked the extra time and effort involved in customizing the operative report for each treated patient. Other larger insurers such as Blue Cross Blue Shield (**BCBS**) asked providers to use a specific S code instead of the miscellaneous code. S codes are temporary codes designated for the private sector that are designed to help an insurer track and monitor usage, often in order to develop a long-term policy for reimbursement.[36] According to Farley, the problem with both of these scenarios was that neither code was associated with an established payment level. "Private payers have their own individual methods for calculating payment levels under miscellaneous codes and temporary codes. And getting a predetermination of a payment level could take an individual provider 6–8 weeks, if it could be obtained at all," he said. Importantly, this uncertainty discouraged some physicians from adopting the new procedure. "Even when the clinical efficacy for your new medical procedure is well established, it's hard to get your business and procedure volume up and running until doctors know precisely how much they're going to get paid," Farley observed.

For roughly three years, providers performing the VNUS procedure billed successfully for reimbursement under the established CPT code, a miscellaneous code, or the S code. During that time, several of the major private payers started to issue negative coverage decisions. "They were not satisfied with the clinical data published to date which was limited to 6 and 12 month follow up of less than 100 patients, and wanted to see stronger evidence that the treatment was safe and efficacious," Farley explained. Fortunately, VNUS had anticipated this issue and voluntarily initiated a large post-market multi-center clinical **registry**. Data from the registry showing elimination of reflux and significant relief of symptoms were published in national and international peer-reviewed journals at a range of follow-up intervals, including six months, one year, two years, and eventually, five years post-treatment. "In addition to providing additional clinical data," said Farley, "the research helped us develop a stronger understanding of the optimal way to perform the procedure and the likely outcomes it would generate."

Encouraged by the positive research findings and convinced that additional clinical data/publications would continue to strengthen its reimbursement and broader commercialization efforts, VNUS had also launched a randomized controlled trial to directly compare its thermal ablation procedure to vein stripping. The first report from the EVOLVeS randomized trial showed short term advantages of the VNUS Closure procedure compared to vein stripping, along with equivalent efficacy. It was published two years after FDA clearance. "That study was the most important study for obtaining positive coverage policy from large private payers and for obtaining local coverage determinations from Medicare," stated Farley. Once the short-term data from the randomized controlled trial had been accepted for publication, the BCBS Association reviewed the VNUS Closure procedure via its Medical Policy Panel and issued a statement that BCBSA had found the procedure to be medically necessary. Farley explained, "The process is that they review the clinical evidence, speak to experts in the field, and then make a decision. But these decisions aren't always final. If new evidence becomes available, a payer may reverse a negative policy into a coverage policy. And, in our case, that's what happened." After BCBSA issued its findings, nearly all of the independent BCBS plans adopted a formal coverage policy over the next nine months.

Eventually, the two-year results of the EVOLVeS trial were published and conclusions from the 80-patient, multi-center trial found the VNUS Closure procedure as effective as vein stripping at two years post-treatment with significantly fewer side effects and a faster recovery time. The data were published in a peer-reviewed article in the *Journal of Vascular Surgery*[37] five years after FDA clearance and contributed to the company achieving of 100 percent insurance coverage in the US.

Around the same time that VNUS resolved its coverage issues, the company experienced another unexpected twist in its reimbursement strategy. A new vein ablation technology had been developed, called endovenous laser ablation (EVLA). EVLA uses laser energy to thermally damage the vein wall and cause the vein to collapse.[38] Use of this technique became popular among interventional radiologists, and it shifted the balance of which specialist treated saphenous vein reflux. Historically these patients were treated by vascular and general/vascular surgeons who had traditionally performed vein stripping. Accordingly, the Society of Interventional Radiologists took the initiative to apply for new codes to cover energy-based vein ablation procedures. The new codes would separately describe and allow different payment levels for RF vein ablation and laser vein ablation. The Society of Vascular Surgery joined in to co-sponsor the application. Once it became aware that this process was underway, VNUS and the laser companies selling EVLA products worked with the two societies to help ensure that the procedures were properly described and valued, providing supply and equipment cost data, and clinical data that had been published in US peer-reviewed journals.

However, despite these efforts, VNUS remained uncertain whether the establishment of new codes would be a positive development for the company. The primary risk was that the payment level recommended by the RUC and established by CMS for the new code would be less than the payment rates physicians had been receiving to date. “We knew there was some risk because we had a good thing going, with almost 100 percent insurance coverage and current payment levels that were adequate,” recalled Farley. At the time, VNUS disposable products commanded roughly a $350 price premium over EVLA in the market, which the company felt was appropriate since it had a more costly catheter that produced better outcomes, as well as less pain and bruising for patient. Plus VNUS had done the “heavy lifting” of pioneering the vein ablation field. “We were first in the market and we had done the randomized trials and published registries. We expected the payment for the new code for our procedure to reflect a higher cost to the customer compared to EVLA,” Farley stated.

Unfortunately for the company, when CMS issued the new codes under which the physician’s time and the cost of the device would be covered, it allowed for a premium of only $175 for radiofrequency vein ablation over EVLA. Because this created a situation in which doctors could make a higher profit by choosing the laser procedure, VNUS lost some market share and was forced to reduce the price of its technology. However, in an almost humorous turn of events, several advocates of EVLA systems responded to the $175 payment differential by launching a letter-writing campaign to CMS, detailing the costs of the EVLA supplies and procedure, and requesting that the reimbursement level for EVLA be raised to be on par with the radiofrequency approach. “But what happened,” said Farley, “was that CMS took a look at the letters, saw that the actual supply costs cited in the letters were lower than what was in the CMS database of practice expense inputs, and it reduced the payment level for laser ablation. This is a classic example of how reimbursement can be unpredictable.” Over the next few years, the payment levels for the two procedures were adjusted until “the payment differential was over $300, close to the way it probably should have been from the beginning,” Farley reported. “The doctors could then make a clinically-based decision to choose the technology that was best for the patient and the profit per procedure would be the same.”

In parallel, VNUS had to address an issue related to the payment level linked to the initial APC code that was assigned to the procedure when it was performed in a hospital outpatient setting. Most VNUS Closure procedures were conducted in the physician’s office, but a reasonable number occurred in the hospital outpatient setting, which necessitated a separate APC code. According to Farley, CMS had two APC codes for vascular surgery procedures and initially placed the VNUS procedure in the lower-paying of the two codes, alongside vein stripping. Aware of the adverse consequences of this lower payment level, executives from VNUS traveled to Washington D.C. with evidence

demonstrating the true costs of the procedure. VNUS argued that the CMS method for determining which APC code is appropriate requires the agency to evaluate the cost of the procedure, but that this analysis had not been conducted. While CMS refused to immediately recode the procedure, it did initiate a process for gathering and assessing cost information. "After a year, their representatives agreed with us, and they moved the procedure into the higher-paying APC code for vascular procedures. From start to finish, it took two years for the actual change of assignment," Farley recounted. In contrast to the letter-writing campaign, he added, "It just shows that if there are mistakes made, and payment levels aren't calibrated correctly the first time, it is possible to make a positive change. It's not fast, and it's not a sure bet, but it can happen."

Outside of the US, VNUS was advancing an equally complex portfolio of reimbursement strategies in select geographies. The preliminary focus was on Europe, noted Farley, "where every country is its own challenge." For example, in the UK, the company started off focusing on private insurers, which gave it access to roughly 25 percent of the population. "It was a small percentage of market, but it was a way in," he said. Eventually, VNUS received a positive technology assessment from the National Institute for Health and Care Excellence (NICE). However, the company had to file a business plan with the National Health Service (NHS) Trust to prove that physicians could perform the procedure outside of an operating theater at a significant cost savings compared to vein stripping performed in the operating theatre. Once that business plan was accepted, the company successfully secured national reimbursement coverage in the UK.

At the time VNUS Medical was acquired by Covidien, the company had sales in 38 countries along with full insurance coverage in the US, UK, and the Netherlands and pending reimbursement decisions in Germany, France, and Australia. According to Farley, approximately 1.5 million patients had been treated with the VNUS vein ablation products as of 2014. "This demonstrates the kind of result that can be achieved with strong clinical evidence and an effectively executed reimbursement strategy," he said.

Reflecting on his reimbursement experience with VNUS, Farley summarized, "Reimbursement for a new medical procedure is often a moving target. From coding through payment levels, no decision is final – early success at obtaining coverage and payment may occur because the procedure is very new and payers have yet to review the data or issue negative coverage policies for it. Also, even after coverage is obtained and payment levels are established, those payment levels are adjusted annual by CMS, and reviewed every five years by the RUC."

The key is to remember that regulatory clearance for a new medical product involving a new procedure is "just the tip of the iceberg," he said. "It's a small part of the overall process of being clinically accepted and commercially feasible." In particular, Farley emphasized the need to develop strong clinical data even if it's not required for regulatory approval. "You have to ask yourself from the beginning, 'What clinical studies do we need to prove to the doctors that our technology is better than the standard of care and demonstrate to payers that covering it is in their best interest?'" Additionally, Farley emphasized the importance of having a sophisticated leader who lives and breathes reimbursement every day, responds quickly to changes in the reimbursement landscape, and can engage other senior company executives in the quest. "It's one of the highest priorities in the company," he stated.

Post-launch support for reimbursement strategy

At the time of product launch, reimbursement support begins with educating providers on key reimbursement challenges and giving them access to the support systems that can help them confirm coverage and secure appropriate payment. The company should educate providers about specific payer requirements in their region, as well as identify payers that support reimbursement for the new technology. If health plans have limited coverage of the device to a subset of the indicated population, physicians and their staff should be trained on appropriate patient selection and prior authorization requirements. Billing staff will require training on plan-specific billing, coding, and claim submission procedures and the claim submission package can be very helpful. The product sales force and/or dedicated reimbursement staff will be on the front lines of reimbursement support and must also be trained to field reimbursement-related questions. Monitoring of payer actions should also take place. Furthermore, appropriate reimbursement expectations should be set with providers, internal stakeholders, and the investment community.

Throughout these support activities, oversight by reimbursement experts and skilled legal counsel will be essential. Practice management support is one of the key areas related to reimbursement that can get companies into trouble. Because supportive information helps providers get paid, in some cases from government payers, great care must be taken to avoid illicit activities that involve kickbacks, inducements, or inadvertent counsel to break the law. A misstep in this area can mean huge fines, bad publicity, and added marketing restrictions from which it could be nearly impossible to recover.

In the post-launch phase, a company may have opportunities to develop mutually beneficial partnership arrangements with health plans. For example, it may elect to work with private payers to track usage and performance outcome measures within their plan population. This type of partnership is often an extension of a contract in which the payer receives a discounted price or rebate by reaching predefined share or volume targets agreed upon with the manufacturer. This provides an incentive to both parties to co-promote coverage. For example, Conceptus Inc. issues a press release each time a new payer adds a favorable coverage policy for its minimally invasive procedure to address blockages in the fallopian tubes.[39] Companies can also use in-office pull-through activities, in the form of co-branded sales pieces promoting the device as "preferred" by this payer. Sales representatives can be used as well, to help advertise coverage policies in order to keep providers informed regarding which payers are reimbursing for the device. All of these activities must be carefully integrated and managed through an ongoing reimbursement strategy.

Online Resources

Visit www.ebiodesign.org/5.6 for more content, including:

Activities and links for "Getting Started"

- Assess the reimbursement landscape
- Perform primary market research with payer decision makers
- Evaluate strategic options
- Develop evidence
- Organize information into a reimbursement strategy

Videos on reimbursement strategy

Appendices that provide additional information about:

- BCBS Technology Evaluation Center
- Common cost models

CREDITS

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