4.3 Reimbursement Basics

INTRODUCTION

Patients interested in a new technology or treatment; doctors committed to delivering it. In most industries, the combination of motivated consumers and capable providers would be a formula for success. But in the healthcare field, one critical factor is missing: the role of payers, or those third-party private or public insurance companies that make the decisions whether or not to pay for (or reimburse) a new medical device. With healthcare costs escalating and few patients able to afford their own medical expenses without insurance coverage, payers (and their reimbursement decisions) are exercising unprecedented levels of influence and control over the adoption of new technologies and, in turn, the direction of patient care.

The purpose of understanding the reimbursement landscape in the early phases of developing a new medical technology is to determine whether or not the existing healthcare payment infrastructure will accommodate a new solution to the clinical need it solves. A reimbursement analysis addresses whether there can be adequate payment for the physicians who would deliver the solution and for the facilities where patients would be treated. It also explores whether or not the coverage would be applicable to a large enough segment of the target market to make the development of the solution financially viable.

This is one of two chapters on reimbursement. This first chapter focuses on understanding the basic landscape for reimbursement and the approach a team or company can take when their innovation fits into the existing reimbursement structure for coding, coverage, and payment. The second chapter, 5.6 Reimbursement Strategy, explores how to expand the existing payment infrastructure to accommodate a new technology if the established payment and coverage levels are inadequate. It also addresses how to develop a comprehensive reimbursement strategy that takes into account the evolving healthcare economics environment in the US and abroad.

See ebiodesign.org for featured videos on reimbursement basics.

OBJECTIVES

- Obtain a high-level understanding of the reimbursement system for medical devices in the US.
- Learn how to identify relevant coverage and billing codes supporting the reimbursement of existing medical devices relevant to a need.
- Understand the status of payment for existing medical device codes, including reimbursement amounts and restrictions on types of patients covered.
- Evaluate differences between US-based private and public payers.
- Survey the reimbursement landscape in select countries outside the US.
- Appreciate how to use reimbursement risks as a screen for prioritizing concepts.

REIMBURSEMENT FUNDAMENTALS

Reflecting on the increasing importance of **reimbursement** in medical device innovation, Thomas Fogarty, the renowned innovator of the embolectomy balloon catheter and dozens of other **medtech** devices, said:[1]

> *Regulatory and reimbursement have always been the two big barriers for devices. I used to focus more on **FDA** and the long and unpredictable path to approval. But FDA seems to be getting better – at least they are working to improve. These days, reimbursement is the biggest worry I have for new technologies that are trying to make it through to patient care. The forces of healthcare economics all seem to be working to keep new technologies from coming forward. **CMS** is not the only problem. Private insurers are a bigger threat. They are going to ask for data before reimbursement that will exceed the requirements of CMS. Watch out!*

In the US, reimbursement for medical devices is handled by both public and private insurance programs. The largest public healthcare program is Medicare, which is a health insurance system for the elderly and disabled that is regulated by the federal Centers for Medicare and Medicaid Services (CMS) with headquarters in Baltimore, Maryland and Washington, D.C. The volume of **payment** transactions by CMS is enormous: each year Medicare processes more than one billion claims from over one million providers.[2] Given its large scale, the Medicare **coding**, **coverage**, and payment system exerts a dominant influence on the US healthcare system and is watched closely by the country's private insurers. The US has hundreds of private insurance carriers (depending on how the businesses are defined), with the largest including UnitedHealthcare, Wellpoint, Kaiser Permanente, Humana, and Aetna. US healthcare spending is split roughly equally between Medicare (20 percent) and private insurers (21 percent), with the remaining portions covered by household spending (28 percent), state and local governments, including Medicaid (18 percent), other private sources (7 percent), and other federal spending (5 percent).[3] Total healthcare spending has already reached nearly $3 trillion, on its way to nearly $5 trillion by 2020 (equivalent to more than 19 percent of the nation's economy).[4]

Against this backdrop, the reimbursement landscape in the US is undergoing fundamental changes that are intended to gradually move away from traditional fee-for-service incentives (that basically reward volume of care) toward new **value**-based programs (that reward quality per unit cost). The passage of the Affordable Care Act (**ACA**) in 2010 was a watershed moment in this transition, mobilizing the healthcare industry to focus on the "triple aim" of improving the experience of care for patients, improving the health of populations, and reducing the per capita cost of healthcare.[5]

Global health insurance systems run the gamut from single-**payer** government systems in many developed countries to predominantly self-pay arrangements that are still common in emerging market countries. While some payment systems are well defined and others are still emerging, each country is characterized by its own unique policies and requirements (see global section later in this chapter).

Whether seeking reimbursement in the US or in any other country in the world, innovators should keep two important points in mind. First, reimbursement policies and procedures are sufficiently complex that innovators almost certainly will depend on experienced consultants to help them develop an understanding of the reimbursement landscape and establish a viable payment approach tailored to specific geographies (see Figure 4.3.1). Second, innovators will almost always achieve reimbursement faster and more easily if they can utilize existing reimbursement pathways for a new technology, rather than having to pursue new coding, coverage, and payment decisions. The determinations of whether or not an existing reimbursement pathway is viable will depend on the nature of the new technology and its match with the existing payment mechanisms, which again may require expert advice and guidance. The main goal of this chapter is to provide innovators with a basic understanding of reimbursement policies and procedures, providing sufficient background that they can collaborate with experts in the field to perform a preliminary reimbursement analysis.

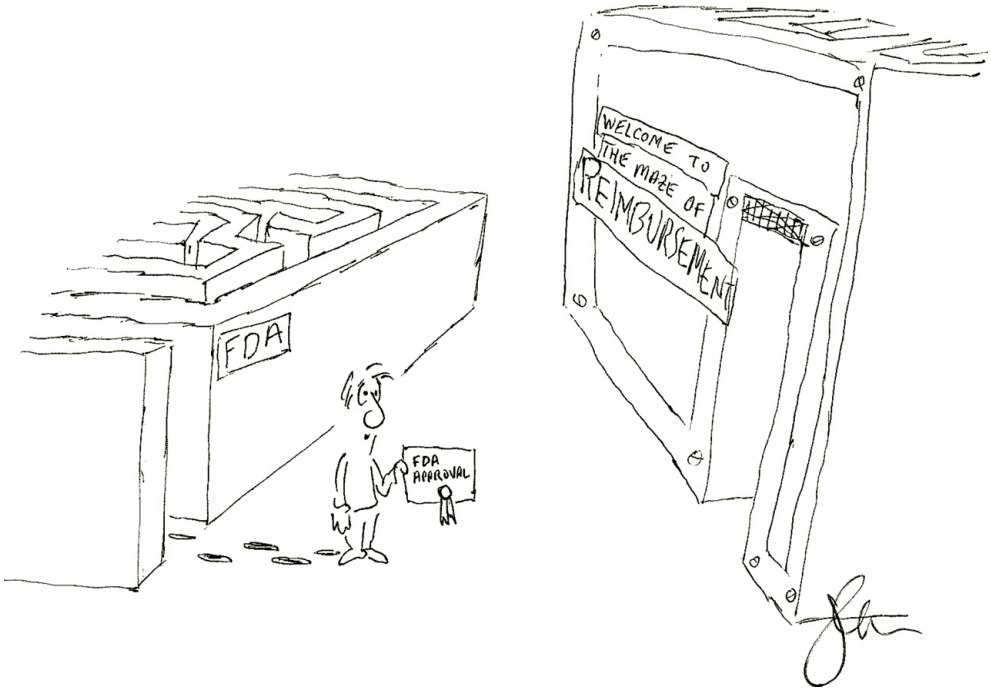

FIGURE 4.3.1
After regulatory clearance, innovators still must navigate a complex maze of challenging reimbursement policies.[6]

Reimbursement in the United States

Both Medicare and private payers in the US follow the same general processes for reimbursing medical services. At a high level, payments are made for medical encounters, which can occur in a wide range of settings: in a hospital (as an inpatient or an outpatient), in an outpatient facility not attached to a hospital, in a doctor's office, or outside of any medical facility. Payments for the physician (or other health provider) and the facility (if the treatment is provided in a hospital or ambulatory health facility) are typically made under separate payment systems. Part of the complexity in the process comes from the fact that there can be multiple payments to the physician and the facility if the encounter involves multiple services.

In its simplest form, the payment process has three main components: Once a service is performed, providers identify one or more appropriate *codes* for the service(s) and provide these codes in a claim that they submit to the payer for evaluation. The payer, in turn, must evaluate *coverage* for the service. If coverage is allowed, the billing codes are translated into appropriate *payment(s)* to the facilities and providers. Each of these elements – coding, coverage, and payment – warrant further examination.

Coding

In short, coding is the language of reimbursement; it tells a payer exactly what was done, how it was done, and why.

In order for physicians and facilities to be paid, they must submit claims to payers using standardized codes to document the diagnoses and procedures performed. Different codes are chosen depending on the setting in which the care is delivered (see Table 4.3.1).

For the *inpatient* setting, billing for both facilities and physicians is based on an identification of appropriate diagnoses and procedures as specified by **ICD-10** codes (this acronym refers to the International Classification of Diseases, 10th revision). At the time of this writing, the use of ICD-10 codes (rather than the **ICD-9 codes** that preceded them) was expected to become mandatory before the end of 2015.[7] There are two types of ICD-10 codes: diagnoses are specified by ICD-10-CM (Clinical Modification) codes, and procedures by ICD-10-PCS (Procedure Coding System) codes. A typical hospital stay

Table 4.3.1 Different codes are used by different parties for the reimbursement of different procedures, services, and supplies.

Provider	Setting	Procedure code	Diagnosis code
Hospitals	Inpatient	ICD-10-PCS	ICD-10-CM
Hospitals	Outpatient	CPT (HCPCS Level I)	
Ambulatory Surgical Centers	Outpatient		
Physicians	Facility/Office		

will be characterized by a primary diagnosis and any secondary diagnoses (with the appropriate ICD-10-CM codes) and, if a procedure or procedures have been performed, by the ICD-10-PCS code(s).

In the *outpatient* setting, facility claims are submitted using different types of procedures and patient diagnoses. Similar to the inpatient setting, patient diagnoses are described using the ICD-10-CM (diagnosis) codes. For procedures or services, a different set of codes are used, called HCPCS. (This acronym stands for the Healthcare Common Procedure Coding System, and is pronounced "hick-picks.") The HCPCS system consists of two levels of codes. **HCPCS Level I** codes are called Current Procedural Terminology (**CPT**) codes. As the name suggests, CPT codes are used to denote procedures and services provided by medical professionals (e.g., physician claims) – again, these are only used by hospitals in the outpatient setting and for physician services provided in any facility or office setting. CPT codes are established and maintained by the American Medical Association (**AMA**), not CMS. **HCPCS Level II** codes are for products, supplies, and services that are used or provided outside of a physician's office and are not included in the CPT codes. For example, level II codes would be used to submit claims for prosthetics, orthotics, or other supplies used outside the medical office. Level II codes would also be used to bill for ambulance services. The level II codes are established and maintained by CMS.

Coverage

In short, coverage determines *if* a technology or procedure will be reimbursed, and under what conditions.

A properly coded claim, submitted to CMS or an insurance company, does not automatically translate into a payment. To grant reimbursement, the payer must have policies in place which state that the procedures, services, and supplies described in the claim are covered by the patient's health insurance plan. These policies specify conditions under which a procedure is covered and provide details about the codes that should be used to submit and justify the claims. For example, coverage policies can stipulate that specific procedures are only covered for certain patient diagnoses, patient subpopulations, sites of service, or other conditions that the payer may specify. Importantly, coverage policies are not uniform and can vary dramatically across payers. In the US, CMS may set national policies (called national coverage determinations, or **NCDs**) that apply to the whole country, or local policies that cover specific regions. For the local coverage determinations, or **LCDs**, Medicare has multiple jurisdictions across the country, each of which is empowered to make separate decisions administering the Medicare program for its region, as long as those decisions do not contradict an existing NCD. In most situations, a company can decide whether to pursue local or national coverage and there are different strategic considerations for each path (which are discussed further in chapter 5.6). Private payers have their own coverage policies, which may or may not align with the Medicare policies.

Payment

In short, payment describes who is paid, and how much. Payment typically varies depending on the setting where the service is provided (e.g., physician office, hospital inpatient, hospital outpatient).

With appropriate codes and coverage decisions in place, the final factor required for reimbursement is

Table 4.3.2 Medicare payment systems are based on the site of the medical encounter and map to the procedure and diagnosis codes.

Provider	Setting	Payment	Procedure code	Diagnosis code
Hospitals	Inpatient	MS-DRG + MPFS	ICD-10-PCS	ICD-10-CM
Hospitals	Outpatient	APC	CPT (HCPCS Level I)	
Ambulatory Surgical Centers	Outpatient	ASC Fee Schedule		
Physicians	Facility/Office	MPFS		

a payment. With Medicare, payment levels are linked to another set of codes that introduce even more acronyms to the reimbursement landscape (see Table 4.3.2).

Medicare payment to hospitals is made under separate payments systems depending upon whether the patient is admitted as an inpatient or treated as an outpatient. Some services are deemed by CMS to be covered only when performed in the inpatient setting, and this list of "inpatient only" services is published annually by CMS. There are specific considerations that factor into whether patients should be classified by hospitals as inpatients or outpatients. Historically, physicians admitted Medicare patients to the inpatient setting if they were expected to require a hospital stay of more than 24 hours or an overnight stay, whereas hospital outpatients typically were discharged from the hospital on the same day. More recently, Medicare requirements have evolved such that CMS issued a "two midnight rule," stating a presumptive expectation that patients should normally be treated as outpatients unless they require a hospital stay crossing at least two midnights (i.e., three calendar days).

Inpatient hospital payments under Medicare are based on a set of payment category codes called **MS-DRGs** (Medicare Severity Diagnosis-Related Groups). A hospital MS-DRG payment is designed to provide a single, prospectively determined payment amount to reimburse for all hospital services that are provided during the hospital stay (tests, procedures, devices, operating room, recovery rooms, nursing services, etc.) except for physician services, which are paid separately under the Medicare physician fee schedule (CPT coding). All services associated with the hospital stay are assigned to a single MS-DRG payment amount. The appropriate MS-DRG payment category is determined from the ICD-10 codes of the primary diagnosis and any secondary diagnoses. The MS-DRG code also takes into account any complications and/or comorbidities and, in some cases, there are specific MS-DRG payment categories that hinge on complications and/or comorbidities. Once the appropriate MS-DRG is determined, the actual payment that the hospital receives is adjusted to reflect local labor costs and conditions. In addition, academic teaching hospitals and hospitals treating a large number of indigent patients receive additional reimbursement under Medicare as part of their hospital-specific DRG payments to account for incremental costs associated with providing those services.

For hospital *outpatient* payments under Medicare (but where the care is still delivered within a hospital facility), an Ambulatory Payment Classification (**APC**) code is assigned to the claim based on the procedure(s) or service(s) performed. This APC code is usually translated or "cross-walked" by the payer based on the CPT codes that are submitted by the hospital. Each APC is assigned a specific payment amount, which is updated annually by CMS.

The major distinction between inpatient and outpatient hospital payments is that inpatient payments are primarily based on patient diagnosis (the D in DRG), whereas outpatient payments are based on the procedures performed in the outpatient setting. Whereas hospital inpatient stays, by design, can only result in a single MS-DRG payment, hospital outpatient stays may result in more than one APC payment

depending on the specific services performed during the outpatient encounter.

Ambulatory surgical centers (ASCs), are designated facilities separate from hospitals or physician offices that perform only same-day discharge services – examples include colonoscopies or uncomplicated orthopedic procedures. ASCs are paid under Medicare based on still another fee schedule, separate from the hospital payment system.

For *physician payments*, the CPT codes are translated into actual payments using the Medicare Physician Fee Schedule (MPFS). Many private health plans in the US also base their physician fee schedules on the MPFS. For the same CPT code, the payment to the physician may vary depending on whether the service was performed in the physician's office (called a "non-facility setting" by Medicare) or in a facility setting such as a hospital or ASC. Payments to physicians also vary by geographic region, reflecting the different costs of practice (such as staff labor charges).

Information about how to ascertain exact payment rates for specific codes is given in the Getting Started section of this chapter. Online Appendix 4.3.1 provides a summary of all the codes introduced above. The Working Examples provided below are also meant to clarify how, when, and why different codes are used to secure reimbursement payment.

More about physician reimbursement

As described above, physicians use CPT codes (HCPCS Level I) to bill for medical, surgical, and diagnostic procedures, regardless of the setting in which they are performed. In parallel, they use ICD-10-CM codes to describe their patient's medical conditions and diagnoses to support their insurance billings and the chosen CPT code.[8] Medicare and private payers, in turn, use the ICD-10-CM codes to audit physician claims and validate the appropriateness of the billing codes used, based on the diagnosis and treatment performed. The following Working Example based on a medical encounter for atrial fibrillation illustrates how billing will proceed in a moderately complicated case.

Working Example
Atrial fibrillation: ICD-10-CM and CPT codes

When a patient with atrial fibrillation seeks treatment, the physician may use the default ICD-10-CM diagnosis code I48.91 to indicate that the patient has been diagnosed with this particular heart rhythm disorder. If the patient is more specifically diagnosed with paroxysmal or persistent AF, a more specific diagnosis code should be utilized (I48.0 is paroxysmal AF; I48.1 is persistent AF; I48.2 is chronic/permanent AF; and I48.91 is unspecified AF) with appropriate documentation in the patient's medical record.

The chosen code would serve as a means of justifying the medical necessity of charges made to a payer for any procedures performed, tests ordered, or services provided related to the management of atrial fibrillation. If the patient has multiple other conditions being evaluated or treated, s/he may have many ICD-10-CM codes noted by the healthcare provider. Again, this is because ICD-10-CM codes are descriptors of some or all of a patient's medical conditions relevant for a particular healthcare encounter.

If the physician performs a cardiac ablation procedure for atrial fibrillation (using catheters maneuvered through the blood vessels to the heart), s/he would likely use CPT code 93656 in billing the payer for this procedure. If additional procedures are performed beyond cardiac ablation, the physicians would use multiple CPT codes to receive payment for all of the procedures performed. See Figure 4.3.2 (step 2) for an illustration of the various codes used by the physician.

Physician reimbursement payments under the MPFS are determined using a Congressionally mandated national fee scale developed by a team of researchers at Harvard University under contract with CMS. The fee scale is called the Resource Based Relative Value System (RBRVS) and is maintained through a joint collaboration process between the AMA and CMS. The AMA's Health Care Professionals Advisory Committee Review Board (HCPAC) obtains

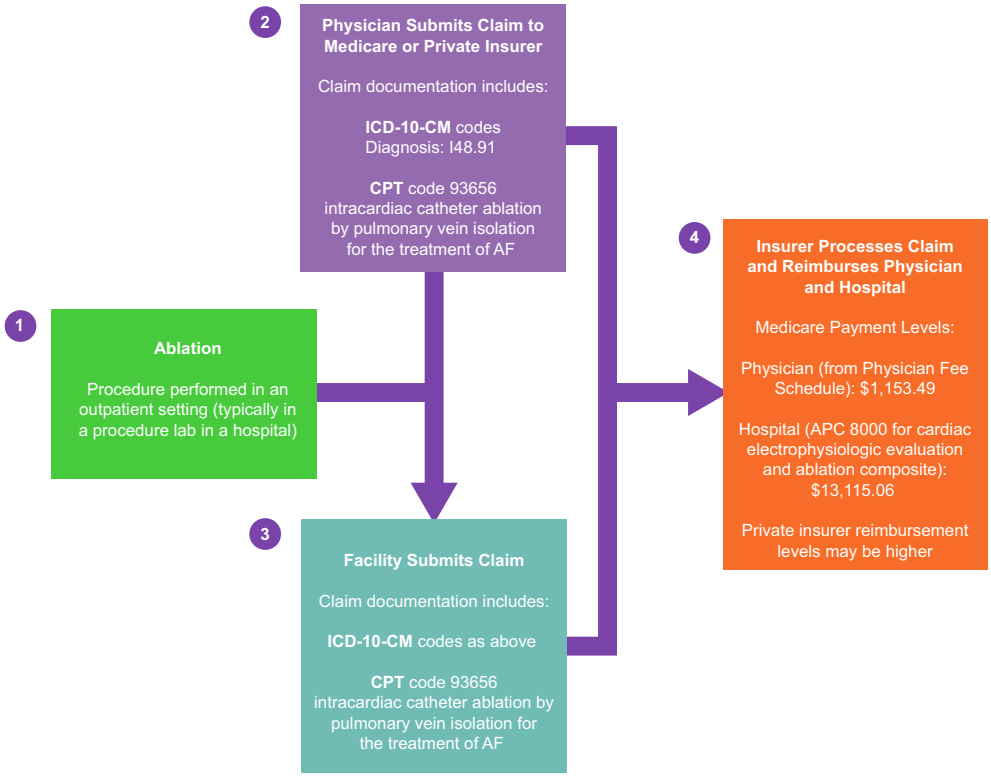

FIGURE 4.3.2
This example for the reimbursement of ablation for atrial fibrillation demonstrates how to trace a procedure through the outpatient reimbursement process. The payment values reflect Medicare national averages across all geographic locations as of 2014.

input from practicing physicians and makes recommendations to CMS on relative value units, or RVUs, for each CPT code. RVUs provide a standardized measure of the resources needed to provide a particular procedure and include three components: (1) a work component, which reflects the time the physician spends on the procedure; (2) a practice expense, which includes nursing time, overhead, and supplies used in the procedure; and (3) a malpractice component that covers liability insurance for the procedure. The number of RVUs is then multiplied by a monetary conversion factor that is determined annually by CMS. The component RVUs may be further multiplied by factors to account for the cost of practicing in different geographic locations (geographic wage index). The result is the final amount Medicare will pay for the procedure or service. The main rationale for using RVUs is that they provide a way of standardizing the measurement of resources and complexity associated with particular physician services across different specialties. Depending on where the procedure or service is performed, there may be two RVUs: a non-facility one for services performed in the physician's office and a facility one for all others. Changes to CPT codes and to the RBRVS are effective January 1st of each year.

Many critics have pointed to weaknesses of the existing fee-for-service Medicare payment systems that determine payments based on the provider's resource inputs rather than the clinical value or health outcomes of the services being provided to patients or the healthcare system. A variety of new "value-based" payment methodologies are being introduced in the Medicare program and by private payers (sometimes alongside or in addition to the traditional fee-for-service payment systems) that are designed to increase rewards for higher-value services while placing increased financial responsibility on providers and patients for lower-value services. This transition will unfold over a number of years, and it will continue to add extra complexity to deciphering the regulatory pathway for a new technology at any given point in time.

Working Example
Atrial fibrillation: physician payment

As shown in Figure 4.3.2, step 4, the payment for performing a cardiac ablation by pulmonary vein isolation (CPT 93656) in an outpatient setting, such as a hospital catheterization lab, is based on the Medicare physician fee schedule. The 2014 national average payment of $1,153.49 was calculated using total RVUs of 32.20 and a conversion factor of 35.83 (which is the same across the US). For specific locations, geographic modifiers are taken into account such that the reimbursement payment would be, for example, $1,238.68 for a physician working in San Francisco.

Note that for physician services including cardiac ablation performed in an outpatient setting, one or more CPT codes may be utilized, as appropriate, to reflect all of the physician services performed for the patient. Whereas CPT code 93656 happens to be a relatively comprehensive code that reflects the majority of the preparation and procedural work involved with the ablation to treat AF, additional CPT codes may also be billable by the physician to reflect three-dimensional electrophysiological mapping (CPT code 93613) and additional linear or focal ablation of atrial fibrillation remaining after completion of pulmonary vein isolation (CPT code 93657) if these services are performed and medically necessary.

More about hospital inpatient coding and reimbursement

As previously described, hospitals apply ICD-10-codes to cover both diagnoses and procedures for inpatient admissions and then translate these codes into the MS-DRG system to determine the amounts of payment. More than 140,000 ICD-10 diagnosis and procedure codes are grouped into over 900 MS-DRGs. Patients within each MS-DRG category are considered by CMS to be similar in terms of their clinical characteristics and resource use, and the hospital receives a single payment amount that reflects the patient's diagnoses and procedures that were performed. For each admission, only one MS-DRG is assigned, regardless of the number of services provided or the duration of the patient's stay. Each MS-DRG has a unique relative weight, which is then converted into the payment amount. Changes in DRG codes are effective October 1st of each year, along with the updates to the ICD-10 procedure and diagnostic codes.

Working Example
Atrial fibrillation: MS-DRG payment categories

If the patient in the atrial fibrillation example is hospitalized for a complex cardiac surgical procedure to treat his/her disease (e.g., a stand-alone open surgical Maze procedure which requires many days of post-operative recovery in the hospital), the hospital would bill using the Maze ICD-10 code and CMS would assign the hospital stay to MS-DRG 228 if the patient had major complications or comorbidities, or MS-DRG 230 if the patient was without major complications and comorbidities. These codes encompass all of the relevant patient care issues (and, thus, relevant ICD-10 codes) that would come up during the procedure and subsequent inpatient hospitalization.

Alternatively, if the patient has a catheter-based cardiac ablation procedure requiring a brief inpatient stay, the hospital might use the ICD-10-PCS codes 025T3ZZ (destruction of left pulmonary vein, percutaneous approach) and 025S3ZZ (destruction of right pulmonary vein, percutaneous approach) for the description of the inpatient service. If Medicare is the payer, this code can get assigned to either MS-DRG code 250 (percutaneous cardiovascular procedure without coronary stent, with major complication or comorbidity) or 251 (percutaneous cardiovascular procedure without coronary stent, without major complication or comorbidity). (Note that MS-DRG codes can be broad, with individual payment categories encompassing a wide array of procedures.)

More about hospital outpatient coding and reimbursement

Recall that hospitals and free-standing outpatient facilities use CPT codes for claiming outpatient services. Under Medicare, each CPT code is assigned by CMS to an Ambulatory Payment Classification (APC) group with a unique relative weight, which is then converted into a payment amount. The APC payment rates are designed to capture all of the hospital expenses involved in the outpatient service (e.g., medical device costs, costs for nurses and technicians involved in the patient's care, procedure and recovery room costs, bundled services such as fluoroscopy, ancillary supply costs, costs of medications such as regional anesthesia, and associated overhead) except for physician services which are paid under a separate fee schedule. Unlike the MS-DRG system, multiple APCs can be assigned and separately paid for as part of a single outpatient encounter, depending on the procedure(s) performed.

Working Example
Atrial fibrillation: APC payment categories

As shown in Figure 4.3.2, step 3, both a hospital and physician could bill CPT code 93656 for a cardiac ablation procedure to treat atrial fibrillation if the procedure is performed in the outpatient setting. Whereas the physician would bill this code to reflect the physician's work to perform the procedure, the hospital bill reflects the hosipital's own costs associated with the procedure, including medical device and ancillary supply costs, nursing and technician costs, procedure and recovery room costs, etc. The Medicare contractor would assign this outpatient service to APC 8000, as shown in step 4, which includes all cardiac ablation procedures as well as associated electrophysiology studies and mapping services that are "**bundled**" into the APC with a national average payment of $13,115.06 for this service.

Reimbursement by private payers

As noted, private or commercial health insurance companies have historically looked closely at Medicare reimbursement and have often followed Medicare's lead in the areas of coverage policy and physician reimbursement. In years past, there was an adage in the US healthcare industry that "what Medicare does, the rest will follow." Although this has generally been true for physician and procedure payments, for hospital payments the private health plans have long negotiated specific contracts with individual hospitals or hospital groups using payment methodologies that differ from Medicare. These include a complex assortment of approaches including "per diem" payments, "carve-out" payments for implantable devices, and all-payer DRGs. In addition, private payers are actively deploying a range of new value-based payment methods that place financial risk on providers and tie payments to performance on hospital quality and outcomes-based performance measures. So, while private payers certainly look to Medicare for direction, they are increasingly likely to make independent decisions based on the goals and objectives of their individual plans. This means that reimbursement decisions can differ not only between Medicare and private payers, but among the hundreds of private payers in the US. This has led to a reimbursement environment in which medical device companies must often seek to establish reimbursement coverage (and appropriate reimbursement rates) on a payer-by-payer basis – a daunting undertaking, particularly for start-ups with limited resources.

Unlike the government, most private insurance companies are in business to make a profit. Even non-profit insurers, such as Blue Cross/Blue Shield (**BCBS**), have goals to maintain their financial health through mechanisms such as increasing their cash reserves (the equivalent of profit to a non-profit company). While patients would like to think that health insurance companies have their best interests at heart, the decisions of these companies may actually be driven by a series of interrelated and complex factors. Patient well-being is certainly among the considerations, but other issues such as profitability, efficiency, and **risk management** also come into play. As one professional association stated on its website:[9]

Insurers are not necessarily in business to assure that everyone receives access to care. Nor are they in business to guarantee that all qualified healthcare providers are fairly and adequately compensated for their services. Healthcare providers often try to assign "moral obligations" to insurance companies, but they are not obligated to accept them. Although the hope is that insurance companies have a basic concern about the health ***needs*** *of the general public and fair payments to practitioners, it should not be expected that this is their primary consideration.*

Generally, as a guiding philosophy, commercial insurance plans state that they cover services that are deemed "medically necessary" by medical doctors. However, the concept of medical necessity is highly subjective and open to interpretation across payers and types of plans.

The two most common types of health insurance plans within the US are health maintenance organizations (HMOs) and preferred provider organizations (PPOs). HMOs bring together healthcare providers (e.g., doctors and hospitals) that have contracted with an insurance company to offer their services as network participants according to a fixed payment schedule and other pre-negotiated terms and conditions. Typically, HMOs are one of the most affordable insurance options available to healthcare consumers. In comparison to PPOs, the premiums for HMOs are relatively low and **copayments** are less expensive (or free). However, in order to offer services at a low, fixed price, many HMOs depend on a high volume of patients and are notorious for being restrictive. HMOs have stringent rules regarding which physician(s) a patient can see and where service can be delivered. From a reimbursement perspective, they tend to place more limitations on what services will be covered, at what rate, and for which patient groups.[10] PPOs, on the other hand, tend not to be as restrictive as HMOs and offer patients a broader range of options.[11] While PPOs contract with medical provider networks, they try to manage medical expenditures through financial incentives (e.g., charging different copayments and deductibles for services performed by network providers versus providers outside the network, charging different copayments for preventive versus corrective treatments, reimbursing certain medical procedures at rates higher than others). In addition, patients have greater choice in choosing a physician, selecting a facility, and managing their medical care in exchange for higher premiums.

As mentioned, Accountable Care Organizations (**ACOs**) are emerging as another type of healthcare entity, stimulated in part by financial provisions of the Affordable Care Act. There are a variety of different ACO payment arrangements and they are rapidly evolving. These voluntary consortiums of *independent* physician groups, hospitals, and insurers share the responsibility for caring for a defined population of Medicare beneficiaries over a defined period of time, but they can earn financial incentives for saving money through more coordinated care that avoids duplicate or unnecessary procedures and tests if they maintain performance on quality and outcomes measures.[12] In general, ACOs have strong motivation to be careful in evaluating new technologies or procedures that have the potential to escalate costs.

Across HMOs, PPOs, and ACOs, the policies of private insurance providers are not created equal. Kaiser Permanente is one major HMO (emerging now as an ACO) that uses stringent **evidence-based** criteria for adopting new technologies.[13] As a result, Kaiser often approves and covers new technologies only *after* they have been thoroughly studied in the post-approval environment and when there is strong evidence (ideally from **controlled clinical trials**) that the new device improves clinical outcomes. Because the process of conducting studies and publishing the results in reputable medical journals can take years to accomplish, Kaiser physicians may be reluctant to use the latest generation of a technology if the evidence behind it is insufficient.[14] Consider, for example, implantable cardiac defibrillators (ICD) used to treat patients with life-threatening cardiac rhythm disorders. While it is undisputed that ICDs help prevent sudden cardiac deaths, new generations of the device include features for which the clinical benefit is not fully supported by the results from extensive **clinical trials**. An article published in the *Permanente Journal* pointed out that while new features, such as dual-chamber and rate responsive pacing, had driven up the

cost of ICDs, most patients do not necessarily benefit from this specialized functionality. For this reason, it advised physicians to consider whether the additional cost associated with the latest technology was justified relative to the potential benefit that each individual patient would receive.[15]

In general, it is necessary for innovators and companies to study their market in determining how much time to invest in understanding the specific reimbursement policies of private payers. If there is a significant Medicare market for the device, understanding Medicare reimbursement practices will be sufficient in most cases. However, if most reimbursement will come from commercial payers, then it will be necessary to invest more time in investigating private payer policies, reimbursement behaviors, and the precedents that have been set by other devices. Some commercial insurers have established groups that specifically evaluate new medical technologies before reimbursement decisions are made. The Blue Cross Blue Shield Technology Evaluation Center (**TEC**) is one well-known example.[16] Many individual plans also post their medical policies regarding coverage and reimbursement on the Internet. Individual payment rates for private insurers, however, can be difficult to obtain from public sources.

The self-pay reimbursement model

Even though government and private payers account for the large majority of healthcare spending in the US, individuals and households finance a full 28 percent of the total.[17] These **out-of-pocket** expenses can include copayments that are a common part of regular insurance coverage, but also self-pay expenditures for elective procedures, such as laser eye surgery or aesthetic and cosmetic interventions, that are typically not covered by insurers. In addition, new types of consumer-directed health savings plans have emerged in which the patient has increased decision-making and financial responsibility for their healthcare decisions.

Innovators should examine carefully whether or not the need on which they are working is appropriate for a self-pay model (see the Miramar Labs story in 5.7 Marketing and Stakeholder Strategy). This approach can be advantageous since it can remove some of the obstacles of reimbursement. However, self-pay also has certain risks and challenges. For instance, the amount of money consumers may be willing to spend out-of-pocket is likely to be much smaller than the amount **third-party insurers** typically pay for procedures. Outside the United States, self-pay is an increasingly important mechanism for reimbursement of new technologies that are not yet covered by government insurance systems, which is a factor that also should be considered (see the global section later in this chapter).

Copayment in reimbursement

As mentioned, a major way that consumers pay directly for healthcare is called "copayment." This is a requirement that patients with a health insurance plan personally pay a certain percentage of the bill, to be collected either at the time of the encounter (e.g., during a clinic visit) or in a subsequent billing. The copay percentage is usually determined by the insurance provider, representing a small portion of the total bill and generally subject to caps. Copayments apply to Medicare recipients, as well as patients covered by private plans. As a rough average, Medicare pays approximately 80 percent of a patient's total bill). Accordingly, many Medicare patients purchase supplemental insurance plans (called "Medigap" plans) that cover most if not all direct copayment responsibilities. With respect to private health plans, copayment levels can differ significantly between insurance plans, with relatively high copayments being one of the major features of less expensive plans. In general, copay levels are becoming an increasingly important factor in reimbursement in the US, and this is contributing to the "consumerization" of healthcare as patients begin paying more attention to the relative costs of procedures and technologies. The implication for innovators is that it is not just the government and private insurance payers who are paying close attention to the cost of new technologies – patients themselves are now comparison shopping with respect to health spending.

Preparing a reimbursement analysis

Before selecting a final **concept**, innovators should have a substantial understanding of the reimbursement environment associated with each of their solution ideas. Such an analysis summarizes the reimbursement landscape for similar or related innovations, including relevant codes, coverage decisions, and payment levels that will potentially serve as precedents for a new technology in the field. The story of Metrika, Inc. exemplifies many of the issues discussed in this chapter, as well as illustrating how basic reimbursement analysis serves as a bridge to the more complex exercise of developing a reimbursement strategy (see 5.6 Reimbursement Strategy).

FROM THE FIELD — POINT OF CARE DIAGNOSTICS IN DIABETES

Evaluating the adequacy of reimbursement under established codes

In the care of diabetes, it is recommended that all patients have a hemoglobin A1C (HbA1C) test twice a year. This test shows the average amount of sugar in the patient's blood for the three months preceding the test. The test results are then used by the patient's physician to adjust treatment (i.e., possibly changing medications and/or modifying nutritional guidelines). Traditionally, the HbA1C test involved drawing a patient's blood in the lab. As a result, some patients skipped testing because of the inconvenience. Michael Allen, a California Bay Area innovator and entrepreneur, came up with a vision for a disposable, convenient, hand-held point of care test for HbA1C, which would enable patients to have their HbA1C tested when they visit their physicians rather than having to take the test in a laboratory setting. Being able to perform the test in the doctor's office had several potential advantages: it was more convenient for patients, it would likely increase patient compliance since there was no second step to the testing process (i.e., the visit to the lab), and it would potentially lead to better management of diabetes because the results would be available immediately so that the physician and patient could discuss them face-to-face in the office. Allen founded Metrika, Inc. to commercialize his idea (see Figure 4.3.3), which was later acquired by Bayer.

At the time Allen was developing his technology, Medicare was reimbursing HbA1C lab tests using the CPT code 83036 (Hemoglobin; glycosylated).[18] That is, labs ("facilities" in reimbursement terms) performing HbA1C tests were using this code to submit their claims to Medicare and were reimbursed at the rate of approximately $13 per test.

The main question in the reimbursement analysis at this point would be whether or not the company could make use of this code to cover its test. The answer (with perfect hindsight) appears to have been relatively straightforward: if the manufacturer could demonstrate that its point-of-care (**POC**) test was equivalent to the existing HbA1C tests performed in the lab, then it would expect to take advantage of the existing code (there is no

FIGURE 4.3.3
The A1CNow+® point of care HbA1C monitor (courtesy of Bayer HealthCare).

reason why Medicare would not be willing to pay the same amount for an equivalent test performed at a different setting, although careful consideration of any **stakeholder** issues arising from a potential threat to a lab's business would be warranted).

The next question to be addressed would be whether or not the reimbursement level associated with the existing code was adequate. To determine this, the manufacturers would have to calculate a rough estimate for their manufacturing cost per test plus a reasonable markup (i.e., margin on that cost). Without knowing the exact numbers for any manufacturer of an HbA1C POC test (since this information is proprietary), one can perform a quick "back of the envelope" calculation using what is known as the "50 percent rule" of approximation. To be viable, the $13 reimbursement rate needed to be sufficient to cover the end **user's** (physician's) cost of acquiring and performing the test, plus a potential markup for the manufacturer. Applying the 50 percent rule, one can infer that the cost of supplies for the physician should be no more than approximately 50 percent of the total reimbursement rate. This means that the price a physician would pay to purchase the test at wholesale would be approximately $6.50 (including shipping and handling). Applying the 50 percent rule again, one can infer that a wholesaler's markup is typically 50 percent, which means that the price a manufacturer could charge the wholesaler for distributing the device would be about $3.25. Assuming that the manufacturer wants and/or needs to make a 50 percent margin on its costs to justify development of the product, the company's production cost would need to be no more than $1.62. This means that the manufacturer should be able to produce the test at a cost of no more than $1.62. If such a cost level is not technically feasible, then any manufacturer must consider seriously whether it should seek a new CPT code and a different reimbursement rate. Alternatively, even if this cost is technically feasible, the manufacturer may want to evaluate whether a value-based argument could be created to support a higher reimbursement and a different code to reflect both the innovation inherent to the POC test and the benefit arising from it.

In the case of the HbA1C POC tests, what actually happened seems to suggest that the reimbursement level associated with the existing CPT code was inadequate to cover the manufacturing costs, manufacturer's margin, and distributor's profits (or that the team felt the innovation in the POC test could justify higher reimbursement). In 2005, the retail price for Metrika's test was $24 (including shipping and handling). Assuming a rough 50 percent profit margin at any part of the value chain (as described above), this means the wholesale price was about $12 per test, the price paid by the wholesaler to Metrika was approximately $6, and production costs per test were about $3. In 2006, the AMA issued a new CPT code (83037). As of 2007, Medicare was providing reimbursement for the Metrika device and the products of its main competitors at $21.06 in most states. Importantly, however, this achievement took seven years from the first FDA approval (September 2000) to the time that the new CPT code was approved by the AMA, accepted by CMS, and associated with a standard reimbursement amount.

A comprehensive reimbursement analysis should include information on the topics shown in Table 4.3.3 for each of the concepts under consideration. Innovators can then use this information to compare the concepts in terms of how difficult or simple it may be to obtain reimbursement for them and the financial viability of the business plan in light of economic and reimbursement considerations. They can also use the information gathered through this research to refine and/or validate key market assumptions (see 2.4 Market Analysis), since it results in new data on the number of procedures performed and total reimbursement granted per procedure.

The steps for completing a reimbursement analysis are outlined in the Getting Started section for this chapter.

Table 4.3.3 Reimbursement analysis should provide innovators with an overview of the current reimbursement landscape for technologies related to the need being studied.

Topic	Description
Payer mix	Identify the primary payer(s) and mix of services by payer.
Location of procedure	Describe the setting in which the new device would be utilized and/or procedure would be performed.
Coverage decisions and technology assessment by Medicare, private payers, and/or health technology assessment agencies	Summarize the coverage decisions for comparable devices and/or procedures, including how long it took to achieve reimbursement and any constraints or exceptions that may affect coverage.
CPT code and payment amount	Define the appropriate CPT code and patient copayment under Medicare or determine if a new code is needed.
MS-DRG, APC, and/or other codes and payment amounts	Define the appropriate DRG, APC, or other code (e.g., HCPCS Level II) and patient copayment under Medicare or determine if a new code is needed.
Facility costs	Summarize the anticipated facility-related costs for the device and/or procedure.
Number of procedures	Summarize the number of procedures performed and reimbursed, reimbursement per procedure, and payer mix.

Global reimbursement

Medical reimbursement outside the US has a reputation for being even stricter than in America. Innovators intending to market products in other geographies have an obligation to carefully understand the reimbursement systems and processes in the countries they are targeting. This section provides a general framework that innovators can use to approach global reimbursement, with an outline of key issues and challenges in major developed and emerging markets.

To understand the reimbursement process for a medical device in any country, the innovator first needs to investigate the basis for financing and delivering healthcare. In most developed nations, there is significant public financing of healthcare from taxpayers, so the government is ultimately responsible for deciding how healthcare funds are distributed to providers. Delivery of healthcare could be public (as in the United Kingdom) or private (as in France). Providers may be allocated a fixed budget from which they are to cover the expenses of all medical services, or they may be paid from the government for each service they provide (using payment processes analogous to the ones in the US). Another model is a hybrid system in which capital expenses (e.g., purchases of expensive equipment or capacity expansions) are covered by a budget allocation, with additional payments granted for each service provided (e.g., variable costs such as physician salaries and supplies). Across the globe, the hybrid systems appear to be the model that is most widely utilized.

It is important for innovators to recognize that the method used to allocate funds to providers is critical, since it is directly related to the adoption of a new technology. As one moves from a fixed budget allocation to a per-service system, the incentives of the providers to use a new technology go up, as long as the technology is adequately reimbursed. Another key issue to understand is whether the purchasing decision and the price paid for a device will be determined through direct negotiations with each provider, or through some global purchasing agreement that involves multiple providers and possibly the government.

High-level reimbursement questions that innovators should ask, for each global market they are considering for device sales, include the following:

- Is healthcare financing public or private?
- Is delivery public or private?
- How are providers paid for health services and for capital expansions?
- Is the volume of services delivered by each provider regulated?
- Are the prices for devices regulated?
- Who negotiates the purchase price and reimbursement level for a device and what is the process used (e.g., direct negotiations between providers and manufacturers, government contracting, or contracting with an alliance of providers)?
- Do new devices have to undergo technology assessment before they can be used and reimbursed?
- Is there a list of approved devices that are reimbursed?
- What is the process for obtaining new technology reimbursement?

With a solid understanding of the answers to these general questions, innovators should next consider the unique aspects of the reimbursement systems in the countries being evaluated. A sample of these issues is provided below for three European and two Asian nations. Innovators must carefully understand the local reimbursement policies and practices of the countries in which they seek to do business, particularly if they anticipate the need to negotiate with government agencies. One way to quickly and effectively learn about national practices is to partner with a local distributor. A strong relationship with an established local player can be a valuable asset in securing reimbursement, as well as setting up an effective sales and distribution infrastructure overseas. In addition, local medical specialty societies and physician opinion leaders can provide valuable information needed to assess and plan for reimbursement.

Germany

In Germany, Europe's largest medtech market, the country's Statutory Health Insurance system (SHI) provides health insurance coverage to approximately 85 percent of the population, with the remainder covered through private health insurance.[19]

The process for the reimbursement of medical devices or diagnostics is highly dependent on the setting in which the product should be used. While CE-certified medical devices may be readily used in the inpatient setting (if hospitals are willing to purchase them and cover them partly or fully from their own budgets), reimbursement of devices and care products in the outpatient and home care setting need to be formally approved by SHI based on applications for reimbursement. Companies must provide supporting information with their applications, including detailed product specifications, data demonstrating safety and quality, and, in some cases, medical or nursing care benefits.[20]

Hospital reimbursement[21] Hospital funding in Germany is regulated by the Hospital Financing Act, which has two primary funding mechanisms. First, payment for inpatient hospital care is the responsibility of SHI (or private insurance), with these payments covering facility, labor, and equipment costs. Second, each state is responsible for covering costs related to capital equipment (assets with an economic life longer than three years). These investments are negotiated between the state infrastructure fund and individual hospitals.

The principle mechanism of inpatient reimbursement is the German DRG or G-DRG prospective payment system. The G-DRG system is maintained by the Institute for the Hospital Remuneration System (Institut für das Entgeltsystem im Krankenhaus, Siegburg), or InEK. This entity is responsible for collecting and analyzing hospital cost data, updating the payment rates associated with each code, and maintaining the codes themselves. The diagnostic and procedure codes that support the G-DRG system are controlled by the German Institute of Medical Documentation and Information (Deutsches Institut für Medizinische Dokumentation und Information, DIMDI). The G-DRG employs ICD-10-GM (German Modification) diagnostic codes, which closely resemble the ICD-10 codes maintained by the World Health Organization. Its procedure codes come from the OPS (Operationen- und ProzedurenSchlüssel) system, which is also maintained by DIMDI.

Reimbursement of new technologies in the German healthcare system depends on the availability of appropriate diagnostic and procedure codes, as well as the uptake and correct coding of this new technology by the hospitals that participate in the InEK calculation system. InEK updates the G-DRG annually, both in terms of its overall DRG code structure and the individual reimbursement amounts. However, the updates are determined based on cost data obtained from the previous two years, so innovators can experience delays in receiving new codes and associated payment rates for new technologies. In response to this lag, InEK created an "on-top" funding process for innovative new products that are not appropriately covered under the current DRG structure and payment amounts. Under the NUB (Neue Untersuchungs- und Behandlungsmethoden) process, individual hospitals can file an application for reimbursement of newly introduced devices. If approved, add-on reimbursement for the use of the technology is granted to the hospital(s) that applied for the NUB payment (not to all hospitals using the product in Germany). Importantly, InEK does not decide on the actual amount of the NUB "on-top" payment. Instead, the payment rate must be negotiated between the hospital and the SHIs. Once an NUB has been granted, InEK monitors usage and cost to determine if the underlying DRG payment should be adjusted, thereby increasing the total G-DRG payment on a nationwide basis. While still somewhat complex and time-consuming to navigate, the NUB pathway can help accelerate market access for innovative new technologies.

Ambulatory reimbursement[22] In Germany, the majority of ambulatory or outpatient procedures are delivered by private practitioners in the community. These physicians are compensated by their regional physician association (Kassenärztliche Vereinigung, KV), which in turn is paid by the SHIs. These payments are generally made on a fee-for-service basis. The physician associations are responsible for distributing payments to their members in accordance with the Uniform Value Scale catalog, or Einheitlicher Bewertungsmaßstab (EBM). The EBM is a fixed budget distribution system, and physicians are only able to invoice services that appear on the EBM. The EBM is maintained by the Kassenärztliche Bundesvereinigung (KBV), the federal association of office-based physicians.

The process to get a new technology for ambulatory use listed on the EBM requires physician support and may involve a health technology assessment by the Institute for Quality and Efficiency in Healthcare (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG). The technology must be specifically approved for reimbursement before it can be used at all, which is different than the inpatient setting, where technologies can be used at the discretion of the hospital unless the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) formally disapproves its use. IQWiG will only endorse new technologies and procedures that are "necessary, appropriate, and economically reasonable." IQWiG does not provide standard guidance for the health technology assessments it conducts for medical devices and diagnostics, but has published its methodology for the assessment process. G-BA maintains a separate Valuation Committee that determines the actual payment for newly listed procedures on the EBM.

France

France is the second largest medical device market in Europe. Healthcare is publicly financed and delivered by both public and private providers. All employed individuals in France, as well as their children and spouses, are covered by the national health insurance plan called Securité Sociale. Individuals who are not entitled to participate in this program (e.g., affluent individuals who are not employed) must purchase special coverage, known as Assurance Personelle. Many people covered by the state-run program also choose to purchase additional insurance to supplement their basic coverage.[23]

Outpatient procedures are reimbursed if they are listed on the Liste des Produits et Prestations Remboursables (LPP) found on the Securité Sociale website.[24] Inpatient procedures are reimbursed using a DRG-system referred to as the Groupes Homogenes de Sejours (GHS). Payments may vary according to whether the procedure is performed in a private or public setting, and the list of approved outpatient procedures may vary according to the setting. Expensive devices may receive an add-on

payment. Public hospitals have a fixed budget to cover all of their capital expenses, so these do not have to be funded by revenue from fees.

When a new device that is not included in the existing lists for the outpatient or inpatient system enters the market, the manufacturer submits a reimbursement application for the new technology and it undergoes a health technology assessment by a special division of the French National Authority for Health (or Haute Autorité de Santé, HAS).[25] This new entity, known as the Commission Nationale d'Evaluation des Dispositifs Médicaux et des Technologies de Santé (CNEDiMTS), was established in 2010 to perform more rigorous health technology assessment and provide scientific opinion concerning the usefulness, interest, and good use of medical devices and other non-drug healthcare products. Based on the recommendation of CNEDiMTS, the Health Ministry then decides whether a device will be granted reimbursement. The Comité Economique des Produits de Santé (CEPS), also known as the Economic Committee on Health Care Products, then negotiates with the manufacturer to set the price or the tariff. They also may set utilization targets and "clawback" provisions for a new technology that can require manufacturers to provide rebates if usage exceeds pre-negotiated targets. The process may take three to four years (or longer). In some cases, innovative medical devices or procedures can be funded temporarily through a dedicated exceptional pathway.[26] This funding covers partial or total reimbursement related to patient stay, the medical device and/or procedure, and the costs of additional data collection. Admission to this exceptional pathway is decided by the Health Ministry with input from the HAS.

As part of the health technology assessment, CNEDiMTS requires a company to submit a reimbursement dossier that includes a technical description of the technology and its mode of action, specifications for use, for which indication reimbursement is required, the severity of the targeted condition, relevant clinical evidence, comparisons existing treatments, and estimates of the size and characteristics of the target population based on epidemiology and/or market research data. Cost/effectiveness analysis is not required but may be submitted with the dossier.[27]

Similarly, CEPS requires the company to submit an economic dossier that includes the recommended price or tariff for reimbursement, sales forecasts up to the market stabilization, price or tariff justification based on cost minimization versus existing alternatives, anticipated sales, and the status of pricing and reimbursement in other EU countries. In addition, CEPS requests a breakdown of costs for manufacturing and distribution, information about the company (location in France and foreign countries for manufacturing and commercialization, number of employees, turnover, and sales information of any other company products sales covered by reimbursement in France).[28] Again, no formal cost/effectiveness analysis or budget impact data are formally required, but they may be submitted for consideration by CEPS.

A more recent development in French device reimbursement and market access is the "STIC" program (soutien aux techniques innovantes coûteuses).[29] This program provides government funding for innovative medical technologies that have already been initially validated by prior clinical studies, but for which no formal clinical and economic evaluation has yet been completed in France.[30] The program aims to establish evidence necessary to determine eligibility for long-term reimbursement. While the trial funding and reimbursement seems an attractive option for innovative device companies, innovators should appreciate that they cannot take an active role in the design and conduct of the study.

United Kingdom

In the UK, the majority of healthcare is provided by the National Health Service (NHS), a publicly funded healthcare system established in 1948.[31] The NHS is organized in Primary Care Trusts (PCTs) and Hospital Trusts with responsibility in their geographic areas. The Department of Health allocates funds to these trusts, which are used to provide necessary medical services and to invest in infrastructure. Trusts reimburse providers for most services using a payment-by-results system, which establishes fixed payments for hundreds of hospital and outpatient procedures.[32] Medical devices reimbursable in the outpatient setting are listed in the drug tariff list.

Inpatient procedures are reimbursed using a DRG system referred to as HRG (Healthcare Resource Groups).[33]

General practitioners (GPs) play a critical role in the UK health system because they serve as gatekeepers for specialized care. Similarly, the PCTs are central to the system because they are charged with financial responsibility for providing optimal care across primary, secondary, and community healthcare services, staying within a given budget.

As the primary payer across England, Scotland, Wales, and Northern Ireland, the NHS has established a variety of mechanisms for evaluating the cost-effectiveness of new medical technologies. In fact, each region has its own approach to health technology assessment (e.g., in Scotland, this function is performed by the Scottish Medicines Consortium and Wales maintains the All Wales Medicines Strategy Group).[34] However, the National Institute for Health and Care Excellence (**NICE**), which is a government organization chartered to issue national treatment guidance and assess cost-effectiveness of healthcare for England, Wales, and Ireland, has become internationally recognized as a model for health technology assessment. In addition to serving as a gatekeeper to reimbursement in the UK, there is growing evidence that NICE guidance is also referred to by other countries since the organization is perceived as having a robust methodology.[35]

Established in 1999 as a department of the NHS, NICE was tasked with producing national guidance on specific health technologies. The organization issues guidance on the use of medical devices and medicines through its technology appraisal process, and also on clinical practice through its guidelines development process.[36]

In contrast to some other countries, NICE does not evaluate all technologies as they reach the market. Instead it selects technologies for review based on factors such as: (1) how likely the technology is to result in significant health benefits across the NHS population if it is given to all indicated patients; (2) how likely the technology is to result in a significant impact on other health related government policies (e.g., reduction in health inequalities); (3) how likely the technology is to have a significant impact on NHS resources (financial or other) if given to all indicated patients; and (4) how likely the institute is to be able to add value by issuing national guidance.[37]

NICE performs its health technology assessments via two routes. The first is the Multiple Technology Appraisal (MTA) process, which commonly examines all relevant drugs and devices within a disease area. The MTA process uses evidence provided by any number of sources, including manufacturers, healthcare professionals, and patient/caregiver representatives. The assessment is made a panel of independent, academic experts from one of a number of academic centers that are commissioned by NICE to perform the evaluation and issue an assessment report.[38] The second route is the Single Technology Appraisal (STA) process. Using this approach, an independent Evidence Review Group is commissioned to evaluate a single technology or drug. The STA process tends to be more streamlined because of its limited scope, with the emphasis placed on evaluating the evidence submitted by the manufacturer.[39]

NICE provides clear guidance on its expectations of what should be included in submissions for its health technology assessments.[40] For both the MTA and STA processes, companies must provide background on the technology, available clinical evidence, cost-effectiveness data, and data supporting the impact of adoption on the NHS. Typically, a health technology assessment from NICE can take 12–24 months.[41]

Although it is a mandatory requirement for the NHS to provide funding in England and Wales for medicines and treatments recommended by NICE, sometimes this funding is delayed due to budgetary constraints. In some cases, device manufacturers can negotiate reimbursement on a **pass-through** basis directly with the trusts.[42]

China

China's healthcare sector is growing rapidly and is expected to provide interesting opportunities for biodesign innovators. In recent years, there has been a gradual shift in the healthcare system with more autonomy being granted by the government to local hospitals and healthcare providers. While the vast majority of hospitals are administered by China's Ministry of Health (MOH), they are now expected to generate revenue to cover as much as 90 percent of their operating expenses.[43] In some

cases, this can create incentives for hospitals to emphasize services they can charge for, such as dispensing prescription drugs.

China's government provides health insurance coverage to approximately 90 percent of the population.[44] However, the state insurance programs are inadequate to cover basic care and instead focus on protecting patients from catastrophic health events. As a result, the Chinese pay for most basic health services out-of-pocket. This dynamic continues to keep modern healthcare beyond the reach of many of China's citizens.

In general, only medical devices that are approved by China's Food and Drug Administration and put in the government regulated pricing formulary can qualify for reimbursement under medical insurance coverage. However, pricing and reimbursement is complicated since it varies significantly by region and at the provincial/municipal level.[45] The Ministry of Human Resources and Social Security (MOHRSS), the National Development and Reform Commission (NDRC), the National Health and Family Planning Commission (NHFPC) oversee the pricing and reimbursement of medical devices in the country. Medical devices are either directly or indirectly reimbursed by the state's Basic Medical Insurance (BMI) Fund (indirect reimbursement may apply to medical equipment used as part of a medical treatment whereas direct reimbursement covers certain medical consumables and implants). MOHRSS, NDRC, and NHFPC jointly issue the National Scope for Reimbursement of Medical Treatments under the BMI, which includes a Non-Reimbursable Catalogue and a Partially Reimbursable Catalogue. Each province may add to or reduce the items in the Partially Reimbursable Catalogue issued on the national level, to the extent that no more than 15 percent of the total items in the national catalogue are altered. The reimbursement ratio is then decided by each province in accordance with their budgets. Patients must pay for any non-reimbursable items, as well as the uncovered portion of partially reimbursed devices.[46]

Overall, the Chinese system remains in flux. The government is working to reform China's healthcare system, with a goal of making basic care available across the country by 2020.[47] However, given the size of the population, the Chinese government is critically concerned about managing healthcare costs. This results in frequent efforts by the MOH to introduce policies that place downward pressure on medical device prices. For example, since 2005, expensive capital equipment (priced more than the equivalent of $730,000) is purchased through a centralized, government-run bidding process.[48] Other cost containment programs have been the subject of experimentation at the local and regional level.

India

The delivery of healthcare in India is provided by both public and private sector entities, although the system is generally considered to be highly privatized. Private providers are responsible for roughly 90 percent of all hospitals, 85 percent of doctors, 80 percent of outpatient care, and almost 60 percent of inpatient care.[49]

In terms of healthcare expenditures, private financing, mostly in the form of out-of-pocket payments by Indian citizens, accounts for approximately 70 percent of all healthcare spending in the country.[50] Estimates regarding the portion of the country's people covered by some form of health insurance vary from less than 15 percent[51] to over 25 percent,[52] although a much smaller number have full or substantial coverage.

Both government and private insurers are working to increase access to health insurance and the industry is growing quickly.[53] According to some estimates, roughly half of the population should have health insurance coverage by 2020.[54] In India, private health insurance programs, group health (in which employers buy insurance for their employees), and government-sponsored health insurance programs are all available. However, public programs cover the majority of patients with insurance, primarily through schemes available to government employees and individuals living below the poverty line. For example, the Rashtriya Swasthya Bima Yojna (RSBY) is one central government program striving to increase health insurance access for poor families.[55] The Central Government Health Scheme (CGHS) is another example that provides health insurance to central government employees, pensioners and their dependents in CGHS covered cities. Although both of these programs face challenges, they represent a start in addressing the country's need for greater health insurance coverage.

In terms of reimbursement for medical technologies, coverage is inconsistent. As one article described, "a patchwork of different government programs sometimes reimburses for devices, but more to public hospitals than to private ones."[56] This heterogenous approach to reimbursement is viewed as less than favorable by medtech companies. For example, in 2013, CGHS reduced its reimbursement rates for drug-eluting stents by up to 60 percent.[57] It also capped prices for angioplasty procedures and bare metal stents. Although the price reductions only apply to individuals covered by CGHS (approximately three million people), hospitals may follow the government's lead in seeking to negotiate lower prices.[58] More broadly, the Ministry of Health is leading discussions regarding government regulation of prices for patented drugs and medical devices.[59]

A final note: using reimbursement analysis to screen and eliminate concepts

As the material in this chapter demonstrates, the analysis of a reimbursement pathway for a new concept can be an extremely demanding and sophisticated task. However, a few high-level factors can be considered during concept screening to help innovators eliminate solutions with killer risks and better understand the opportunities and challenges associated with the others to help populate the risk scoring matrix described in 4.6 Final Concept Selection.

Because reimbursement has such a profound impact on the success of a new innovation, it is worth the time and effort to make a best-guess estimate of the reimbursement pathway at this point in the process. The key questions to ask are outlined below.

1. **Will an established code work?** Achieving reimbursement for a new technology will almost always be faster, less complicated, and less expensive if a company can utilize existing codes. When evaluating established codes, innovators should determine if the new device and its usage is mismatched in any way to the existing descriptor for the most relevant code(s). If so, the language of the code may need to be expanded or a new code required. Importantly, minor differences in the indications or procedure associated with the new device relative to the established code descriptor can be grounds for a payer to reject the new device for reimbursement. Even if new codes are required, the presence of applicable existing codes may serve as a "bridge" for the company until new codes, coverage, and higher reimbursement can be secured (this strategy is discussed further in chapter 5.6).
2. **What are the cost implications?** When evaluating the presence of existing codes, another essential factor to consider is if the payment level associated with the code is adequate to cover the new technology and the procedure used to deploy it. As mentioned, codes (and the payments associated with them) are typically issued to describe procedures, not just the technologies. Accordingly, the payment for an existing code has to adequately cover costs to the facility and/or the time of the physician (and other involved care providers) in performing the procedure, as well as the cost of the technology. Innovators sometimes find that an appropriate code exists to describe their new procedure, but the established payment level is insufficient to cover the technology and adequately compensate the facility and/or provider(s) for their time.
3. **When is a new code worth pursuing?** If the concept under consideration could truly represent a breakthrough in clinical care, it may be worthwhile to move forward despite the fact that a new reimbursement pathway is required. In this case, innovators need to be realistic in estimating the time and cost involved in establishing new coding, coverage, and payment, and then be prepared to present this picture to investors. Here it can be useful to look at other technologies with similar regulatory requirements and clinical impact that have made it through the system to achieve reimbursement (and, in so doing, have engaged with relevant clinical experts and medical specialty societies). Even with a precedent of this type, it is important for innovators to take into consideration the fact that the current healthcare environment (with its emphasis on economics) is less friendly to new technology adoption than it has been in past decades.

Online Resources

Visit www.ebiodesign.org/4.3 for more content, including:

- Activities and links for "Getting Started"
  - Identify payer mix
  - Confirm location of procedure
  - Research coverage decisions and ICD-10/CPT codes
  - Investigate reimbursement information for non-covered devices
  - Identify payment categories (MS-DRGs, APCs) and reimbursement rates
  - Identify number of procedures
- Videos on reimbursement basics
- An appendix summarizing U.S. reimbursement codes

CREDITS

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NOTES

1 All quotations are from interviews conducted by the authors, unless otherwise cited. Reprinted with permission.

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