TCG

WHITE PAPER

Securing Reimbursement for Innovative Medical Technology

Getting payment is often more difficult than gaining FDA clearance.

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Many innovative medical technologies that gain FDA clearance end up as commercial failures because companies are unable to secure reimbursement. Securing adequate payment is often more difficult than gaining FDA clearance. This is complicated by the fact that each insurer is free to decide both what it will pay for, and how much it will pay.

The United States healthcare reimbursement and insurance landscape, with many different public and private insurers, is fundamentally different than the single payer systems in Europe and Asia. While the FDA process is fairly well designed and certainly all under the authority of a single agency, the process to get sufficient payment for a new medical technology is not well defined, and is not under the authority of any single agency or company.

There are a number of reimbursement coding systems, each of which may or may not apply to a given product. Underlying all coding systems is the ICD-10 system, or International Classification of Diseases, 10th revision. This is owned and maintained by the World Health Organization, and is used by medical providers around the world. The United States uses four main coding systems that are associated with ICD-10 codes. These coding systems are:

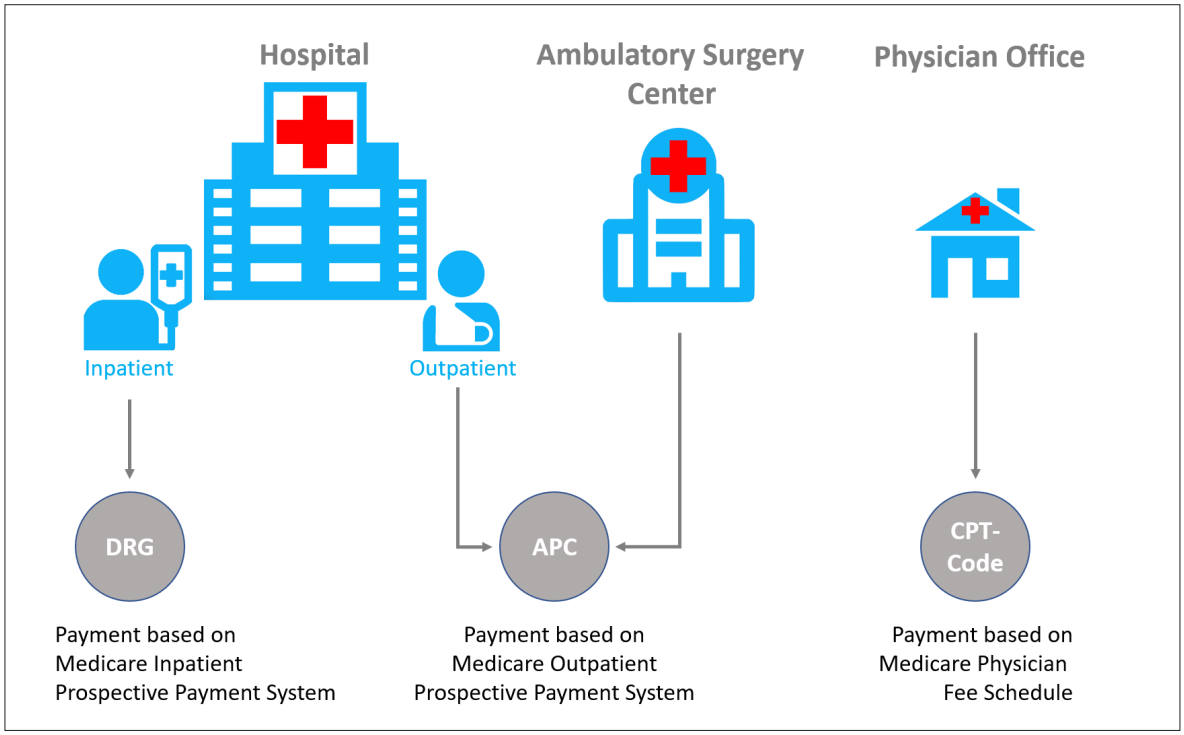
➔ Diagnostic Related Groups (DRGs), which are Medicare's coding system for acute care, inpatient hospital stays.
➔ Ambulatory Patient Classifications (APCs), are the hospital outpatient counterpart to DRGs.
➔ Current Procedures Terminology (CPT) codes, which are owned and maintained by the American Medical Association, are used to determine payments to physicians and facilities where they provide services, usually in an office, or non-acute care setting.
➔ Healthcare Common Procedure Coding System (HCPCS) is managed by the agency that runs Medicare, and enables extra payments for expensive devices and biologics used in treating patients.

Find the relevant coding system

The relevant coding system for a given product will depend on the type of product, the procedure it will be used for, and where the procedure is done.

If a product falls within a relevant DRG, APC or CPT reimbursement code it does not guarantee that the product is covered by insurance, however. Reimbursement refers to the level of payment. Coverage means whether a given technology or procedure is paid for by insurers.

There are different public and private insurance payers each with its own coverage policy and payment amounts. Medicare, administered by the Center for Medicare and Medicaid Services (CMS), is the federal program that covers all Americans 65 and over. Medicaid, which covers low income Americans, is a federal program but is administered by individual states Private insurers, such a UnitedHealth cover most Americans through their employers. Private insurance is also available to self-employed individuals on the federal health exchange under the provision of the Affordable Care Act (ACA), or "Obamacare". Each of these insurers makes its own decision whether it will cover a product in an established DRG, APC or CPT code, and how much it will pay. One insurer may cover a given product, while another may not. Insurers are often resistant to covering innovative, novel products and may demand additional evidence of a product's clinical and economic value, or its impact on improving the quality



Basic overview of Medicare reimbursement system for services and procedures for Hospitals, Ambulatory Surgery Centers (ASCs) and Physicians offices and facilities.

of patient care, before establishing coverage and pricing.

Codes and categories

A new device may fall into one of several broad categories:

➔ Category 1

The technology falls within existing codes, which allows for adequate reimbursement. Examples would be competitively priced devices used in accepted surgical procedures such as a new hip replacement. In this case, no reimbursement work is needed beyond the initial assessment.

➔ Category 2

The technology falls within existing codes, but the level of reimbursement is too low to support the product.

➔ Category 3

No existing code describes the new technology, and thus a new code is needed.

If an assessment shows that a new device falls into Category 1 above, the company can be confident that key product features, not economics, will determine its success. This category also applies to new technologies that add cost, but allow a hospital to save money during a hospital stay (by shortening the length of stay, for example). In this situation, additional reimbursement work is not needed, but hospitals will want to see strong evidence that the savings are real.

Category 2 is common for advanced products aiming to replace older, established products. Companies have several options here. In the short term, academic medical centers (which receive significantly higher reimbursement

than non-academic centers for both inpatient and outpatient procedures) might be willing and able to pay for a premium product as it may enhance their image against competing local hospitals. Academic centers want to be seen as having the latest technology and capable of doing the most difficult cases. A company can focus on academic medical centers (of which there are hundreds) while working toward the creation of a new code.

Bringing new technology to market

Bringing an entirely new technology to the market that does not fall under any existing code is a significant undertaking. It is possible to get new codes created for outpatient procedures, although the process takes several years. However, it is unrealistic to aim to get a new inpatient code created for a new procedure. Few new DRG codes (Medicare's inpatient coding system) have been created in the 35 years the system has been in place.

Whether the goal is a new code, or convincing hospitals of costs savings within existing codes, strong clinical data is paramount. This will almost always mean conducting clinical studies above and beyond any that are required for FDA clearance. The surest way to get coverage for a new device or procedure is to get the endorsement of the relevant medical society. If a medical society, such as the American College of Cardiology or the American Academy of Neurology, includes a technology in its periodic Practice Guidelines, that is the most important step in getting a new code created or getting insurers to pay a premium price even before a new code is created. Most medical societies have coding and reimbursement committees. Committee members will almost always be widely published academic physicians within the field. These doctors can easily distinguish between strong and weak clinical studies. Ideally, they want to see blinded, randomized, multi-center studies showing outcomes that justify premium pricing or new codes altogether. And the larger the potential patient population is for a new technology, the higher the standards for compelling clinical data.

Proof of concept

TCG Partner Nat Bowditch has been able to get a new CPT code created, and convinced a professional society (the American College of Cardiology) to include a new diagnostic procedure in its Practice Guidelines. Nat has also received favorable coverage recommendations for new technologies from several Insurance Technology Assessment Committees, including the widely watched National Blue Cross/Blue Shield Technology Evaluation Committee. TCG can perform a Reimbursement Assessment to identify issues and develop and implement a plan to put a new medical product on strong economic footing in the United States.

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