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Summary

- Reimbursement refers to the complicated process by which physicians and hospitals deliver products and services and then receive payment from third-party payers.
- Reimbursement consists of three factors: coding, coverage, and payment.
- The Current Procedural Terminology (CPT) codes include category I, II, and III codes, each with a different purpose and criteria.
- Requesting a new CPT code for a new device is a complicated and lengthy process, so an early understanding of the process is important to identifying the necessary resources.
- Working with CPT code consultants and a medical specialty society can help a startup obtain new CPT codes to ensure reimbursement for new medical devices, or determine if the new device fits within an existing CPT code.

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Reimbursement Strategies and CPT Codes for Device Development

Tai-Yun Kuo, MB,¹ and Scott Manaker, MD, PhD²



Topic Relevance by Timeline

Summary

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- Working with CPT code consultants and a medical specialty society can help a startup obtain new CPT codes to ensure reimbursement for new medical devices, or determine if the new device fits within an existing CPT code.

Introduction

Bringing a medical product or service to market is a challenge. An academic entrepreneur needs to understand the entire commercialization process and manage multiple tasks related to early-stage research and development, clinical trials, regulations, and reimbursement. The goal of receiving Food and Drug Administration (FDA) approval is often considered the ultimate endpoint that leads a new technology to commercial success. However, getting marketing approval does not

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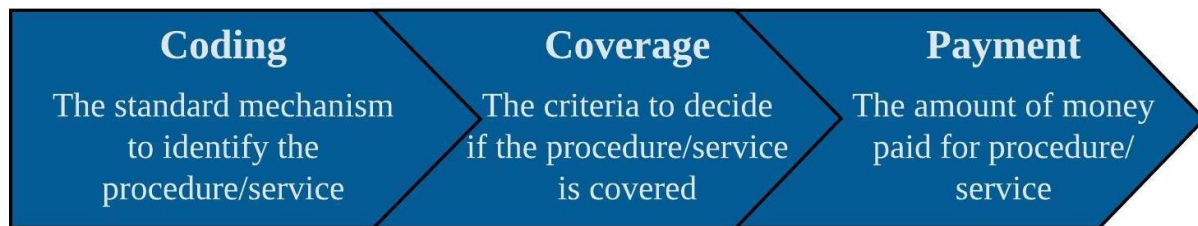
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guarantee market success. For example, if new products do not obtain the desired amount of reimbursement or, even worse, are not covered by payers, then physicians and hospitals are highly unlikely to buy and utilize the new products. Therefore, ensuring reimbursement for the new product can be as important as obtaining regulatory approval. It usually takes several years to plan and execute a successful reimbursement strategy. Hence, instead of waiting for market launch, the company should start reimbursement planning in parallel to developing the regulatory strategy.

Healthcare Reimbursement

Healthcare providers provide medical services to a patient and typically receive payment for these services from third-party private or government payers. This process, called reimbursement, involves complex rules, regulations, and management (Stark and Jaeger). Individual payers evaluate products based upon their own criteria, and not all payers may reimburse for a given service. Understanding the reimbursement decision process is essential for academic entrepreneurs to develop an ideal strategy that will complement and enhance sales success (Figure 1).

Figure 1. Reimbursement Decision Process.



The three parts of reimbursement are coding, coverage, and payment. The code is a standard alphanumeric sequence that describes drugs, medical devices, and medical and surgical procedures and services. Coding is intrinsically linked with coverage and payment. Healthcare providers use these codes to bill payers for services (and associated costs) rendered to patients. There are several types of coding systems with different purposes. For example, CPT codes describe medical, surgical, and diagnostic procedures. The International Classification of Diseases (ICD) codes, established by the World Health Organization (WHO), are also alphanumeric diagnostic codes that state the symptoms, area, and type of injury or disease in a patient.

Coverage refers to whether payers will or will not pay for a specific medical product or service. Coverage decisions, of course, depend on FDA clearance or approval of the product or service, following the provision of sufficient evidence to demonstrate the efficacy and safety of a new medical device over the existing technologies (see the chapter “FDA Device Regulation: 510(k), PMA”). Different payers have particular coverage criteria to determine whether or not the new product or service is reasonable and necessary or is considered experimental and investigational. In other words, the coverage decision influences the payment determination for new technologies.

Payment is the amount of money that is transferred from payers to healthcare providers who use the new technology. The payment is based on a fee-for-service model, which means that payers pay a fee for the service or procedure associated with the medical device, instead of for the device itself. The payment amount is influenced by multiple factors, such as product price, coding, and contracts between providers and payers.

The successful reimbursement strategy has two major objectives. One goal is demonstrating medical benefit and added value to secure coverage, based on clinical study evidence. Second, the device company must identify the appropriate existing coding for the new product or recognize the need to create a new or revised code. Because medical device reimbursement primarily depends on the coding system, the absence of the correct code may prevent payment for a device or service.

A CPT Code Is the Key to Medical Device Reimbursement

CPT codes are a uniform and widely used code set that describes medical procedures and services performed by physicians and other qualified healthcare professionals. They are the system used by major federal programs (Medicare and Medicaid) and private insurance companies throughout the United States. Therefore, understanding CPT coding is crucial for academic entrepreneurs to ensure reimbursement for their medical device and product innovations.

The history of CPT code development

The American Medical Association (AMA) established the first edition of the CPT in 1966, helping to communicate mainly surgical procedures for insurance claims and basic information for statistical purposes. In 1970, the AMA published the second edition, an expanded five-digit coding system describing diagnostic and therapeutic procedures in surgery, medicine, and various specialties. The fourth edition, issued in 1977, introduced a periodic updating system that could keep up with the rapidly changing healthcare landscape. The CPT was adopted as part of the Healthcare Common Procedure Coding System (HCPCS) developed in 1983 by the Healthcare Finance Agency (HCFA, the predecessor to the current Centers for Medicare & Medicaid Services, CMS). Afterward, the HCFA (and now the CMS) required Medicare and Medicaid to use CPT codes. Subsequently, CPT coding is extensively used to describe healthcare services between providers, public payers, and private insurers throughout the country (“CPT® Overview and Code Approval”).

The three categories of CPT codes

Category I CPT codes

Category I CPT codes are mainstream procedures and services with a five-digit numeric code. For example, 33512 represents coronary artery bypass, vein only, four coronary venous grafts. Category I CPT codes are released annually on January 1. To warrant a category I CPT code, the procedure or service must meet the following criteria (“The CPT Approval Process”):

- Received FDA approval or clearance;
- Performed by many physicians across the United States. However, there is no definition of “many,” and thus the device creator will need guidance from the affiliated specialty society whose members would use the code;
- Performed with a frequency appropriate for the intended clinical use;
- Consistent with current medical practice;
- Well-proven and documented clinical efficacy in U.S. peer-reviewed literature.

Category II CPT codes

Category II CPT codes are supplemental tracking codes that describe performance and measurement, purposed for collecting information on the quality of care and thus reducing administrative burdens on healthcare professionals. These alphanumeric codes consist of a four-digit number followed by the letter “F,” such as 0001F (composite measure), and new codes are released three times a year, in March, July, and November (“The CPT Approval Process”).

Category III CPT codes

Category III CPT codes are temporary codes for emerging technologies and are used to facilitate data collection and track performance. Category III CPT codes have five characters: four numbers followed by the letter “T” (for instance, 0058T, cryopreservation, reproductive tissue, ovarian). The AMA releases new category III codes twice a year, in January and July, and the codes usually remain active for five years.

The main difference between a category I and a category III code application is that a category III code application does not require FDA approval/clearance or proven clinical efficacy (see the chapter “FDA Device Regulation: 510(k), PMA”). But a category III code needs to satisfy the following specific criteria: First, the procedure or service must be currently or recently performed in humans. Second, the procedure or service has to meet at least one of the following additional criteria (“The CPT Approval Process”):

- Supported by at least one CPT or Health Care Professionals Advisory Committee (HCPAC, whose members represent qualified non-physician healthcare professionals) society that would use this procedure or service;
- Actual or potential clinical efficacy supported by peer-reviewed literature;
- At least one institutional review board (IRB) approved protocol of a study;
- A description of a current and ongoing United States trial outlining the efficacy.

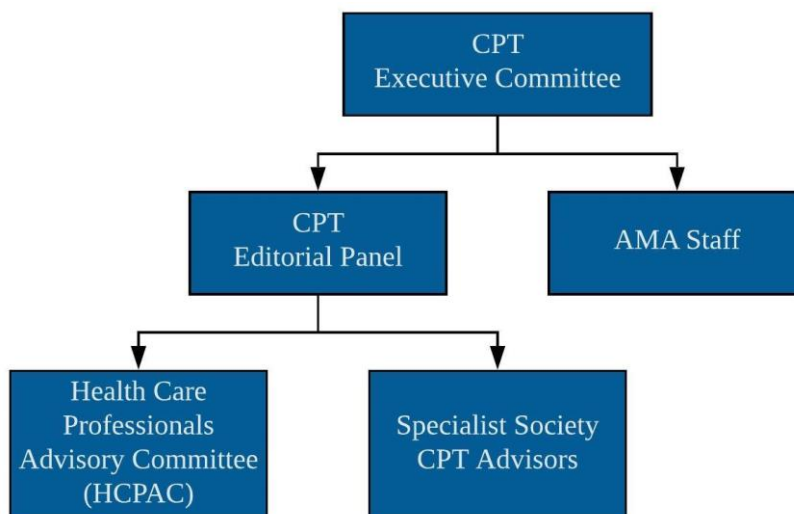
How to Get CPT Code Approval

Who reviews and evaluates CPT code applications?

The CPT Editorial Panel is responsible for maintaining, revising, and updating the CPT code set (Figure 2). The panel comprises 17 members, including 11 physicians nominated by national medical specialty societies; 4 physicians nominated by the CMS, the Blue Cross Blue Shield Association, America’s Health Insurance, and the American Hospital Association; and 2 members of the CPT HCPAC. Five members of the panel serve as an executive committee that supervises the work of the full Editorial Panel, as well as the AMA staff. Applicants disputing a decision from the Editorial Panel can request an appeal.

The executive committee first receives the applications for consideration, determines whether to accept or reject each application, and makes a recommendation to the full Editorial Panel for the final decision. Additionally, the CPT Advisory Committee serves as an expert resource to the Editorial Panel, advising on the coding applications. The Advisory Committee comprises representative physicians selected by the national medical specialty societies from the AMA House of Delegates and the HCPAC.

Figure 2. Multi-layer CPT Governance.



The CPT code process

If a device creator concludes that no existing CPT codes adequately describe a new procedure or service, an individual physician, medical specialty society, third-party payer, or any other interested party can submit the CPT code change proposal (CCP). The CCP must adhere to the posted timeline on the AMA website. Therefore, the applicant has to carefully understand all requirements and plan to submit the request within the appropriate time frame (“The CPT® Code Process”).

Step 1: Submit the CCP

The complete CCP must provide the following information:

- A complete description of the procedure/service, including a detailed description of the skill and time involved. (For example, an operative report can be included to describe the detailed surgical procedure);
- A clinical vignette that describes the typical patient and the procedure/service;
- The diagnosis(es) of patients for whom this procedure/service would be performed;
- A copy of publications in U.S. peer-reviewed journals demonstrating the safety and effectiveness of the procedure, as well as the frequency with which the procedure is performed, and/or estimation of predicted performance;
- A copy of additional published literature that clarifies the request;
- Evidence of FDA approval for the device used in the procedure/service, if required (e.g., for category I codes).

Step 2: AMA staff review the request and determine whether it is new

If the Editorial Panel has already addressed this request, the AMA staff will notify the applicant of the panel's coding recommendation. However, if the AMA staff determine that the request is a new issue or includes significant new information on an item that the panel reviewed previously, the application will move to step 3.

Step 3: CPT Advisory Committee and HCPAC review and comment on the application

After reviewing the application, if the Advisory Committee agrees that no new code is needed, the AMA staff will inform the requestor on how to use existing codes for the new procedure. On the other hand, if the committee determines that a change should be made, AMA staff will assemble agenda material, including the committee's opinions and submitted documents, for the CPT Editorial Panel review.

Step 4: CPT Editorial Panel review and meeting vote

Panel members receive agenda materials before each meeting. They review the applications and comments from the CPT advisor, and confer with experts on each subject, as appropriate. The panel meets three times each year (exact dates are listed in the CPT calendar on the AMA website) to address nearly 350 major topics per year, typically involving more than 3,000 votes on individual items ("FAQ: CPT® Applications"; "CPT® Editorial Panel Meeting Process Calendar"). The possible decisions are

- add new code or revise existing nomenclature;
- refer application to a workgroup for further study;
- postpone an item to obtain further information;
- reject a request.

Step 5: AMA staff inform applicants of the panel's decision

Applicants who receive a rejection of their submission can request reconsideration if they believe that the panel's decision is incorrect ("FAQ: CPT® Applications").

Step 6: Panel meeting minutes posted for specialist society and public review

Once the new/revised CPT codes are approved, the panel meeting minutes are then reviewed and approved by the relevant specialist society. Ultimately, all approved new and revised codes are then referred to the AMA/Specialty Society RVS Update Committee (RUC) for review and recommendation of physician work relative value units and direct practice expense inputs. The RUC recommendations are then forwarded to the CMS, and the CMS incorporates these recommendations along with all other public comments into the federal rulemaking process that governs the Medicare program.

Step 7: Implementation of the new/revised CPT code

The AMA releases the new CPT book, including annual updated new codes, in the fall of each year to allow effective use on January 1 for most category I codes.

The entire new CPT code application process can take from 18 to 24 months. Moreover, it may take two to five years to collect all the literature and evidence that meet criteria. Therefore, engaging with reimbursement consultants experienced in CPT applications early in the process is key.

How to Develop Strategies to Achieve Product Reimbursement

When writing the business plan, do not forget to include reimbursement strategies with adequately estimated costs and timelines (Gold). Starting a reimbursement landscape strategy early and proactively approaching medical specialty societies can help maximize the market opportunities for new technology. It is crucial to identify the key stakeholders and cultivate strong relationships (see the chapter "Forming and Maintaining Meaningful Partnerships Between Academic Scientists and Corporations").

Payers

The first step is to know the main payer types and their differences. In the U.S., payers include Medicare, Medicaid, and private insurance companies. The startup team should identify the target market of the product, including indications and demographics of the target patient population. Then they should find suitable payer types that can support the reimbursement costs and ensure market access to the new product. For example, assuming the targeted customer is an elderly patient population, Medicare will be a major payer.

Key Opinion Leaders

Key Opinion Leaders (KOL), often the principal investigators of the clinical trials, help evaluate the efficacy and safety of new medical devices in peer-reviewed journals. In addition to clinical professionals, KOLs can advocate and support the product and data collection during the entire development process. It is imperative to educate KOLs on coding systems, insurers, and related issues, such as the publication plan for meeting the criteria for CPT code applications. KOLs can facilitate the reimbursement process by providing clinical support and valuable perspectives.

Specialty societies

There are hundreds of specialty medical societies, and they play a key role in evaluating coding systems. It is important to choose the right societies whose specialist physicians will use the product. The startup team can then ask these societies for help to guide the team through the reimbursement process, especially the CPT code application, and work to ensure that these societies remain supportive throughout the process.

Determine Codes for New Technologies

The newly developed device might fit the applicable codes in the current CPT index. However, a company might recognize gaps in the current coding system that would require new codes to be obtained. Before submitting the request for adding codes, the AMA suggests reviewing the following questions:

- Is the suggestion a fragmentation of an existing procedure/service?
- Can the suggested procedure/service be reported by using two or more existing codes?
- Does the suggested procedure/service represent a distinct service?
- Is the suggested procedure/service merely a means to report extraordinary circumstances related to the performance of procedure/service already included in CPT?

Develop a Publication Strategy

A publication strategy communicating clinical outcomes is necessary for meeting the literature requirements for a code application. A successful strategy involves the collection and dissemination of new clinical data for the medical device, and it ensures that the necessary data is released on schedule when approaching the desired audience. Note that peer-reviewed journal publications are preferred by major stakeholders because they recognize the credibility of such journals. The startup team should consider the timeline and identify when clinical studies will be concluded, when the data will be analyzed and ready for conference presentations and manuscript submissions, and how much time to allow from manuscript acceptance to final publication. The second step is selecting key journals and conferences for the dissemination of data. An enduring element through this process is ensuring agreement with investigators to conduct trials and publish data aligned to this schedule.

Conclusion

Academic entrepreneurs devote considerable effort and time to developing innovative medical devices. The ultimate goal is distributing the new technology to the market successfully so that it can benefit patients. A sound reimbursement strategy with appropriate CPT codes can help a medical device be widely adopted, create value for physicians and patients, and generate revenues for the company. Three categories of CPT codes (I, II, and III) are used to track mainstream services/procedures, measure performance, and monitor emerging technologies, and each category has its own criteria and literature requirement. Fitting a product into the CPT code schema requires the support of physicians and medical societies. Working with a reimbursement consultant early on maximizes the likelihood of commercial success and saves time and costs.

Resources

1. Current Procedural Terminology
 - a. American Medical Association, www.ama-assn.org/amaone/cpt-current-procedural-terminology.
2. Fixing Medical Prices: How Physicians Are Paid
 - a. Laugesen, Miriam. *Fixing Medical Prices: How Physicians Are Paid*. Harvard University Press, 2016.
3. Case Example: Fractional Exhaled Nitric Oxide.
 - a. Manaker, Scott. "Fractional Exhaled Nitric Oxide." *Chest*, vol. 149, no. 5, May 2016, pp. 1123–25, <https://doi.org/10.1016/j.chest.2015.12.007>.
 - b. This editorial describes an example that highlights the coverage determination problems discussed in this chapter.
4. CPT®Codes: What Are They, Why Are They Necessary, and How Are They Developed?
 - a. Dotson, Peggy. "CPT®Codes: What Are They, Why Are They Necessary, and How Are They Developed?" *Advances in Wound Care*, vol. 2, no. 10, 2013, pp. 583–87, <https://doi:10.1089/wound.2013.0483>.

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