The Importance of Wound Care Researchers and Manufactures Working with Medical Associations When Bringing New Products to the Marketplace

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Every day products and their accompanying procedures are delivered to the marketplace and touted to aid physicians and other qualified health care professionals (QHPs) in taking care of patients who have chronic wounds. Some of these products/procedures have been developed with the patient in mind and with a serious regulatory and reimbursement strategy, and other products/procedures make physicians, other QHPs, and payers scratch their heads about the true purpose of the product/procedure. Researchers and developers often only focus on gaining Food and Drug Administration (FDA) clearance and often plunge into the marketplace unaware of the reimbursement stumbling blocks that can prevent the expected market acceptance. Researchers and developers should simultaneously plan for FDA clearance and reimbursement from the product's inception. If a product/procedure requires a new procedure code, researchers and manufacturers should seek the help and guidance of professional medical associations to navigate the Current Procedural Terminology (CPT®; CPT is a registered trademark of the American Medical Association), to make available useful new products/procedures for appropriate patients and to adequately reimburse the physician and other QHPs.

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INTRODUCTION

TECHNOLOGY IS DEVELOPING at a rapid pace within the medical community. At every wound care conference, physicians and other qualified health care professionals (QHPs) see new and interesting products/procedures and wonder whether they can benefit their wound care patients and whether the payers will reimburse the product and/or the procedure. The researchers and developers of these wound care products/procedures must create a step-by-step strategy for gaining Food and Drug Administration (FDA) clearance, for acquiring new product/procedure codes, for earning coverage by the payers,

and for gaining adequate allowable payment rates from the various governmental and private payers to enable their new product/procedure to not only enter the marketplace and benefit the patients with chronic wounds but also to pay the physicians and QHPs for their affiliated work.

WOUND CARE PROBLEM ADDRESSED

Many wound care products manufacturers do not think about applying for codes for their new products/procedures until after they have navigated the FDA clearance process. This is unfortunate because the

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language used in the FDA application must align with the language used in coding applications. In addition, manufacturers often look at coding applications, which appear rather straightforward, and (1) think they can complete the applications without the assistance of an experienced consultant and (2) think they can navigate a coding process like the Current Procedural Terminology (CPT®) process by themselves.¹⁻²

For example: During this author's term on the Board of Trustees of a respected professional medical specialty association, several medical device companies came forward and sought the association's advice and guidance to maneuver through the CPT maze. One such group of researchers came to the association after attaining FDA approval, after unsuccessfully maneuvering the gauntlet of the CPT Panel on their own, and after not quickly launching their product/procedure to the wound care market as they had hoped. Rather than reach out to the professional medical specialty association in the early product/procedure development stage, they came seeking assistance and a more scandalized approach after they had failed at navigating the CPT process. Because the professional medical specialty association staff and policy gurus are extremely knowledgeable about the CPT process and have developed an outstanding network within the CPT Editorial Panel, this device/procedure was able to gain a new CPT code in <2 years. Unfortunately, the researchers wasted the prior 2 years trying to navigate the CPT process themselves. This scenario is repeated many times a year and highlights the importance of networking with one or more professional medical specialty societies to improve the chances of receiving positive CPT codes the first time through the CPT process.

DISCUSSION

Several years ago, Martin Gold described a formula for successfully gaining new codes. Let us review that formula that is still relevant today.

Early on, a strategy should be developed that includes not only a business plan for product/procedure development but also a reimbursement plan that may allow for features that are reimbursable to be built into the product/procedure as it is developed. This will help to ensure viability of the product/procedure as it proceeds through acceptance at both the provider level and the payer level.³

Also, early on, researchers and developers should decide whether the product/procedure will

be targeted to a certain payer mix or whether it will be targeted toward a wide range of payers. For example, will this product/procedure be specific for patients with Medicare benefits or will it also be applicable to patients with private insurance (Blue Cross, Anthem, Aetna, etc.). Either way, the researchers and developers will need to proceed through the Healthcare Common Procedure Coding System (HCPCS) to gain a code for the product, and/or to navigate through the CPT process to gain a code for the procedure.

Once the payer mix has been determined, researchers and developers should research whether any comparable technologies are already in the marketplace and whether one or more of those technologies have codes, coverage, and payment (the three major components of reimbursement). Knowing whether comparable products/procedures are already in use and identifying where they are on the pathway to reimbursement may aid the development of a reimbursement strategy for researchers' and developers' new products/procedures.

As the reimbursement strategy process is developed and implemented, researchers and developers often need additional input on practical application as it pertains not only to use of the product/procedure but also to supply and logistics within the health care system. This is the time to seek the expertise of key opinion leaders (KOLs) as well as to connect with professional medical specialty societies that represent the areas of medicine for which the product/procedure is intended.

Medical Advisory Boards can be used to gain a better understanding of real-time product use and application that might have been overlooked in the design process. These medical advisory boards (be sure to also include a reimbursement specialist) can also be convened to share real-time reimbursement knowledge about the product/procedure and may uncover alternative pathways of reimbursement or even a different classification category for the product/procedure.

Researchers and developers should select KOLs who are willing to engage their own professional medical specialty societies to lend assistance in the CPT process because unspoken "politics" is always at play throughout the CPT journey. Credibility of the KOLs and of their professional medical specialty societies, as well as a lack of financial incentives for the societies involved, plays a crucial role in the CPT process, which can take as long as 3 years or more to complete.

Researchers and developers should also try to select KOLs who have participated in one or more CPT work groups. The KOLs on these work groups

will provide the product/procedure development team a better understanding of the CPT process. Work groups are an integral part of the CPT process because they engage several different stakeholders in the development of options that the CPT Editorial Panel can consider in reaching a final CPT coding determination. If a work group is convened to work on the researchers' and developers' product/procedure CPT coding application, thought leaders and KOLs who can objectively contribute insight and use data to pertinent CPT work groups can result in positive CPT coding outcomes.⁴

Connecting with professional specialty medical societies opens communication pathways between the reimbursement team working with the new product/procedure and the society members who do battle in the trenches of the CPT and HCPCS committees. This dialogue will prove to be invaluable when the product/procedure is discussed at these coding committees. Familiarity with the design, function, and intended purpose of the product/procedure by professional medical specialty society members can make or break a coding determination.⁵

The CPT Editorial Panel, by definition, is tasked with ensuring that CPT codes remain current and reflect the latest medical care provided to patients. Although it can be debated as to the timeliness of the CPT process, it nonetheless is the backbone of the health care coding system for physicians and other QHPs. The CPT Editorial Panel meets three times a year to collect and distill the direct input of practicing physicians, medical device manufacturers, developers of the latest diagnostic technology, and advisors from >100 professional medical specialty societies who represent a myriad of physicians and other QHPs.

Professional medical specialty societies and nonphysician health care professional societies, their coding and nomenclature committees, or their equivalents that develop and review proposed changes to the CPT code set, and their CPT/Health Care Professionals Advisory Committee (HCPAC) Advisors are central to the CPT process. Therefore, it is crucial that these societies' practices, policies, and procedures, pertaining to the CPT process, must be recognized as fair and objective by all stakeholders. Professional medical specialty societies should follow and, where appropriate, urge industry and other parties to follow the CPT Editorial's Panel policy on lobbying and to direct CPT code applicants and others to

the CPT staff for guidance, if need be. Professional medical specialty societies should explain their level of assistance from the onset to be transparent as to their availability and their timetable for such assistance.

Professional medical specialty societies select their CPT Advisors based on their knowledge of the CPT process and medical coding, and their commitment to objectivity. Although professional medical specialty societies are not required to assist code change participants or prospective applicants, including industry or commercial interests, in the development or review of CPT code change proposals, they are encouraged to assist researchers and developers to assure that code change requests are complete, coherent, and consistent with current medical practice and coding standards.

In recent years, one piece of the CPT code application has gained increasing importance. Evidence-based medicine now plays a significant role in the CPT Editorial Panel's decision-making process when it comes to use of products and procedures. Professional medical specialty societies constantly ask for and look for data to support the claims made by the device/procedure researchers and developers. Having published data, for example, and randomly controlled trials and other forms of scientific research, now plays a large role, not only in clinical use but also in gaining new codes and appropriate reimbursement. However, professional medical specialty societies must not demand that applicants submit literature demonstrating clinical efficacy that exceeds the threshold of evidence established by the CPT Editorial Panel.⁶

SUMMARY

In summary, working with Medical Advisory Boards, KOLs, and professional medical specialty societies (who have detailed knowledge of the CTP process) has been demonstrated, time and time again, as the key to navigating the step-by step CTP coding application process. This collaborative work from the inception of the product/procedure can shave months or years from the usual tortuous and sometimes confusing pathway to CPT code approval, which is usually required before payers will reimburse physicians and other QHPs to use the new product/procedure.

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TAKE-HOME MESSAGES

- Develop a reimbursement strategy for new products/procedures at the same time the FDA strategy is developed
- Engage Medical Advisory Boards, KOLs, and professional medical specialty societies early in the development of new products/procedures
- Request assistance, to navigate the CPT code application process, from the professional medical specialty societies of your KOLs
- Understand the timeline involved within the CPT process
- Be sure that those who are speaking for your device are aware of the politics at play and the position that this product/procedure will have in the marketplace.

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Abbreviations and Acronyms

CPT = Current Procedural Terminology
 FDA = Food and Drug Administration
 HCPCS = Healthcare Common Procedure Coding System
 KOL = key opinion leader
 QHP = qualified health care professional