Tips for Navigating the Healthcare Common Procedure Coding System Coding Process for New Devices

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Obtaining an appropriate Healthcare Common Procedure Coding System (HCPCS) code for a new product is the first step in a successful reimbursement strategy. However, applying for a new HCPCS code can be a frustrating, confusing, and complex process even for those who have prepared and submitted applications many times. Although the Centers for Medicare and Medicaid Services (CMS) staff provide excellent instructions for the various steps of the process (such as completing the application and presenting at the public meetings), the uninitiated and even veterans can learn tips from those who have been involved in this process for many years. The planning for a new HCPCS code should take place well in advance before the submission actually takes place. The company's reimbursement staff should be involved early in the product research and development and clinical trial discussions. This article addresses the strategy and activities that companies should undertake before applying for a new HCPCS code. In addition, the article also addresses key milestones in the HCPCS coding process, such as completing the HCPCS code application, attending, and speaking at the HCPCS public meeting.

Keywords: reimbursement, HCPCS coding, medical devices, Centers for Medicare and Medicaid Services, scientific research, Food and Drug Administration

INTRODUCTION

TO HAVE SUCCESSFUL commercialization of a new medical device, manufacturers need an appropriate Healthcare Common Procedure Coding System (HCPCS) code for their product. Although the process of obtaining a new HCPCS code may seem simplistic to the uninitiated (just fill out an application and submit it to the Centers for Medicare and Medicaid Services [CMS]), it takes thoughtful and strategic planning. When a company is making the decision to create a new device, part of that analysis should include not only assessing the opportunity and developing the risk analysis and competitive landscape, but also determining the regulatory,

reimbursement, and clinical pathways and ability to achieve the necessary result. A previous article in *Advances in Wound Care*, "HCPCS Coding: An Integral Part of Your Reimbursement Strategy,"¹ addressed the importance of developing a coding, coverage, and payment strategy and emphasized that obtaining an HCPCS code is the starting point for allowing patient access to new and innovative technology. That article focused on HCPCS definitions, decisions on whether the company needs to obtain a new code or apply to use an already existing HCPCS code, and issues to consider when applying for a new HCPCS code. This article focuses on how best to position the product and

includes tips to obtain the best outcome after the company makes the decision that a new HCPCS code is needed. These tips cover critical activities that will increase the odds of obtaining an affirmative decision to one's application, successfully navigating the HCPCS coding process, completion of the HCPCS code application, and attendance and presentation at the HCPCS public meeting.

DISCUSSION

Issues to consider before submitting a new HCPCS code application—plan ahead!

- **Integration of Food and Drug Administration (FDA) and reimbursement strategy:** Recognize that how the new product is cleared and classified by the FDA will impact on how the CMS HCPCS Workgroup regards it. Although the FDA 510(k) clearance pathway may be the quickest way to the marketplace, if the product is a truly unique technology, consider other FDA pathways that distinguishes it from other products on the market. *Tip:* A company cannot expect that if it chooses the 510(k) pathway (which declares the new product is substantially equivalent to a predicate device), then it cannot state in the HCPCS application that the new product is totally different from the predicate device. Consistency between the new product's FDA clearance and the HCPCS application is paramount. However, if the company still chooses the 510(k) pathway, and still chooses to seek a new HCPCS code, it should be prepared to (1) clearly articulate why this item is the same or is similar to another item for FDA clearance purposes and (2) justify the issue of a new unique HCPCS code for coverage and payment. If the company cannot clearly articulate, justify, and support its position, it needs to reconsider its FDA and HCPCS approach.
- **Clinical data:** The HCPCS code application requests scientific evidence to demonstrate how the new product results in a significantly improved medical outcome or significantly superior clinical outcome. *Tip:* The company should conduct studies to demonstrate safety and efficacy for FDA that will satisfy both the FDA and CMS requirements. This coordination will save the company both time and money. Additionally, the type of data submitted to CMS is important.

The company should review the evidence requirements to establish a superior clinical outcome.

This should include a strong understanding of the questions that must be answered in the HCPCS coding application: what clinical need is the item intended to address; what segment of the population needs the item, including clinical indicators; and under what circumstances is the product needed over other similar products and why. Then, the company must determine the research mechanism (highest achievable level of evidence) or combination of mechanisms that will answer these questions and then publish the results in a peer-reviewed medical journal. Reprints of published studies should be included in the HCPCS coding application. The company should be aware that case series with a small number of participants may not be enough scientific evidence to warrant a new HCPCS code.

- **Sales data:** The HCPCS code application requests submission of 3 months sales data after product launch. Obtaining sales can be challenging in the absence of a unique HCPCS code; still, the company needs to create a sales and marketing plan for selling the new product before it has an HCPCS code. *Tip:* Consider first selling to Veterans Administration, Workers Compensation, or others that do not require the use of HCPCS codes. Another option is to meet with Medicare DME MAC (Durable Medical Equipment Medicare Administrative Contractor) and PDAC (Pricing Data Analysis and Coding Contractor) Medical Directors or Medicaid staff and gain support for the product and agreement that a miscellaneous code may be used for submitting claims for the new device.
- **Data required for a product that is designed for use by patients insured by private payers or Medicaid rather than by Medicare:** The company should contact these payers and obtain their support in the form of a letter that can accompany the HCPCS code application or to be independently sent to the CMS staff. These support letters are critical to show a national program operating need. *Tip:* Start this process early because obtaining this support and the letters takes a significant amount of time and effort.

Mistakes to avoid when completing the HCPCS code application

The HCPCS code application and instructions for completion are on the CMS website.² To ensure accuracy, the company should carefully review the instructions for completion and submission of the

application. Following are tips to help manufacturers avoid submitting what is termed an “incomplete” application, which will not be accepted by the CMS.

- Answer every question on the HCPCS code application. Some companies may not answer a question if they think it does not apply to the new product or may omit important information. For instance, one company did not include the full name and description of the product, which stopped the HCPCS application process until the required information was submitted to the HCPCS staff. *Tip:* Review the HCPCS code application multiple times before submission to ensure it is complete, and remember to sign and date it. Consider having the application reviewed by someone without strong knowledge or understanding of the product, because he/she is more likely to identify omissions or responses that are not clear.
- Be truthful on the HCPCS code application. Do not say the product performs more than the FDA allows. *Tip:* The HCPCS Workgroup reviews the FDA market clearance letter along with the HCPCS code application. If the two documents contain contradictory information, the new product will not receive a positive preliminary HCPCS code decision.
- Know the audience when describing the new technology. Although the HCPCS Workgroup does include some physicians/clinicians who are familiar with medical technology, the company should explain the new product scientifically to demonstrate its uniqueness but should use terminology that all the HCPCS Workgroup members will understand. *Tip:* Use complete terms rather than acronyms and do not assume that the application reviewers understand the new technology. Again, having someone outside the company review the application may be useful.
- Understand the care settings where the new product will be used (*i.e.*, physician’s office, patient’s home, hospital outpatient department) because they must be identified both in the HCPCS code application and at CMS HCPCS public meeting. *Tip:* The HCPCS coding process is for items used in the outpatient area (such as the patient’s home, physician’s office, hospital outpatient department) and paid by Medicare Part B. A new product will not usually be awarded an HCPCS code if the company states that the new product is primarily used in care settings such as the operating room, acute care hospital, or skilled nursing facility.
- Use correct terminology, in the HCPCS code application, to describe the new product. For instance, if the product is a cellular and/or tissue-based product for skin wounds (CTP—previously known as skin substitutes), do not describe it as a “wound dressing” or “wound cover.” *Tip:* Both the CMS and FDA use different terminology to describe some wound care technologies. If the manufacturer does not use the correct terms in the HCPCS code application, the new product might not be awarded the anticipated HCPCS code. Although the FDA might use the term “wound cover” to describe a CTP, the CMS staff will believe that the term describes a surgical dressing that is coded differently from and is in a different benefit category (a supply vs. a biological) than a CTP.
- Pay attention to the number of pages in the draft HCPCS code application. The maximum is 40 unless the application includes relevant substantiating clinical information. *Tip:* The 40-page limit includes the FDA clearance letter, package insert, product brochures, and other supporting documentation.
- Do not submit, if possible, the HCPCS code application the week of the application deadline (first week in January). Mail it early so that there is enough time to reach the appropriate department of the CMS in Baltimore. HCPCS code applications cannot be hand delivered like they could be in past years. *Tip:* Manufacturers can submit HCPCS code application anytime throughout the year. Companies who do not wait until the last minute to submit the application have an advantage. If the HCPCS code application is sent early enough, the HCPCS Workgroup staff will review it and contact the manufacturer if they have a question or request additional information if something is missing that is needed to make the application complete.

Tips for participation in the HCPCS public meeting

In the spring after the January code application deadline, the CMS publishes the HCPCS Workgroup’s preliminary coding decisions and announces the summer dates for the HCPCS public meetings.³ These meetings allow the HCPCS code applicant another opportunity to advocate for a new product

code. This is especially important if one receives a negative determination. The CMS posts well-written guidelines that provide excellent advice for participation⁴ in the public meetings. Wise applicants read the guidelines and carefully follow them. Even if manufacturers have attended HCPCS public meetings in previous years, they should read the guidelines for the current year's meeting because the guidelines are subject to change every year.

Following are some tips that should assist manufacturers prepare for a successful presentation at the public meeting:

- CMS publishes the preliminary coding decisions and announces the public meeting dates in the spring. *Tip:* Check the CMS website on a regular basis because the date the preliminary coding decisions are posted, and the date of the public meetings are often quite close. This short notice often requires a quick turnaround for the manufacturer to identify its primary speaker, to prepare and submit a PowerPoint presentation, and to make travel arrangements.
- Selection of a primary speaker. *Tip:* Speakers, who are typically well received by the CMS HCPCS Workgroup, should be articulate physicians and clinicians who are leaders in their field, who use the product successfully in their practices, and who can address the research associated with the new product.
- Best approach for selection of the primary speaker if the preliminary coding decision is negative. *Tip:* Although the first instinct is to select a company representative (who knows the new product very well) deliver the remarks, that person is often not the best choice. Company representatives may deliver their remarks in anger (out of frustration with the HCPCS process) that unfortunately does not help their situation. Selection of a key opinion leader such as a physician/clinician who can speak passionately, but objectively, and can provide reasons for disagreeing with the negative preliminary coding decision is typically a wise choice.
- Best approach for selection of the primary speaker if the preliminary coding decision is

TAKE-HOME MESSAGES

- Consider hiring a reimbursement consultant who is experienced in completing HCPCS code applications and is knowledgeable about the HCPCS coding process. Although at first blush the HCPCS code application seems simplistic to complete, a seasoned consultant will understand the details that the HCPCS Workgroup expects.
- Preplan to achieve the best results.
 - Before companies submit for a new code, they should review CMS's decisions listed on the website,³ begin to develop a list of required information, and begin to draft the document. Knowing the application requirements provides guidance for all stakeholders to develop the new product's regulatory and reimbursement strategies. They should allow ample time to accommodate multiple reviews and edits before actually submitting the final HCPCS application.
 - If the new product is truly unique, discuss with your regulatory consultant or lawyer as to which FDA pathway is best to pursue. Although the 510(k) pathway may be quickest way to market, this pathway may not be beneficial in the long-term, especially if the new product requires a new HCPCS code. A question on the HCPCS code application asks why the existing HCPCS code(s) for the 510(k)-predicate product(s) do not adequately describe the new product.
 - Providing the highest achievable level of evidence or combination of research mechanisms in a published peer-reviewed medical journal is essential if the company is making a claim of significant therapeutic distinction. Because the trials need to be more robust than simple case studies, the company needs to work early on with clinicians to perform and publish the trials before submitting an HCPCS code application. Then it is very important for the company to include these published clinical trials in a new HCPCS code application.

positive. *Tip:* If it is possible for a company representative to attend in person, he/she should take the opportunity to graciously thank the HCPCS Workgroup. A simple "thank you" will do. Additional information is not necessary.

- Know the coverage and payment rules that may be associated with the new product. *Tip:* Knowing what products/procedures are bundled together versus paid separately is helpful in recognizing whether the new product will be eligible to receive an HCPCS code.
- Be succinct and to the point. *Tip:* Speakers should not belabor issues that may cause them to lose the audience's attention. This may cause important messages that are delivered to be missed or forgotten.

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Marcia Nusgart, RPh is the founder and Executive Director of the Alliance of Wound Care Stakeholders (“Alliance”), a nonprofit advocacy trade association of physician specialty societies, clinical and patient associations whose members treat or are patients with chronic wounds. The Alliance addresses regulatory and legislative issues impacting wound care. She also serves as Executive Director for the Coalition of Wound Care Manufacturers and President of Nusgart Consulting LLC.

Ms. Nusgart is an industry leader in providing comprehensive strategies to medical device and pharmaceutical manufacturers regarding coding, coverage, and reimbursement issues under Medicare and Medicaid.

In May 2008, she founded the Alliance for Healthcare Common Procedure Coding System

(HCPCS) II Coding Reform to seek improvements to the HCPCS coding process so that it is fair, transparent, predictable, understandable, timely, and accountable. The Alliance comprises law and lobbying firms, associations, medical device companies, and reimbursement consulting companies.

As Executive Director of the Alliance and the Coalition, she is viewed as a highly visible, respected, and credible source of industry information for the Centers for Medicare and Medicaid Services and their contractors, Food and Drug Administration, Medicare Payment Advisory Commission, and the Agency for Healthcare Research and Quality as she advocates for appropriate public policy processes. Ms. Nusgart sits on four boards, including the Ohio State University College of Pharmacy.

REFERENCES

1. Nusgart M. HCPCS coding: an integral part of your reimbursement strategy. *Adv Wound Care* (New Rochelle) 2013;2:576–582.
2. Centers for Medicare and Medicaid. <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCS-Application.pdf> (last accessed on July 25, 2018).
3. Centers for Medicare and Medicaid. <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCS-PublicMeetings.html> (last accessed on July 25, 2018).
4. Centers for Medicare and Medicaid. <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-ParticipationGuidelines.pdf> (last accessed on July 25, 2018).

Abbreviations and Acronyms

CMS	= Centers for Medicare and Medicaid Services
CTP	= cellular and/or tissue-based product for skin wounds
DME MAC	= Durable Medical Equipment Medicare Administrative Contractor
FDA	= Food and Drug Administration
HCPCS	= Healthcare Common Procedure Coding System