Marcia Nusgart, RPh

Submitted for publication June 4, 2013. Accepted July 5, 2013.

*Correspondence: Executive Director, Alliance of Wound Care Stakeholders, 5225 Pooks Hill Road Suite 627 South, Bethesda, MD 20814 (e-mail: marcia@woundcarestakeholders.org).

HCPCS Coding: An Integral Part of Your Reimbursement Strategy

Marcia Nusgart*

Executive Director, Alliance of Wound Care Stakeholders, Coalition of Wound Care Manufacturers, Bethesda, Maryland.

The first step to a successful reimbursement strategy is to ensure that your wound care product has the most appropriate Healthcare Common Procedure Coding System (HCPCS) code (or billing) for your product. The correct HCPCS code plays an essential role in patient access to new and existing technologies. When devising a strategy to obtain a HCPCS code for its product, companies must consider a number of factors as follows: (1) Has the product gone through the Food and Drug Administration (FDA) regulatory process or does it need to do so? Will the FDA code designation impact which HCPCS code will be assigned to your product? (2) In what “site of service” do you intend to market your product? Where will your customers use the product? Which coding system (CPT® or HCPCS) applies to your product? (3) Does a HCPCS code for a similar product already exist? Does your product fit under the existing HCPCS code? (4) Does your product need a new HCPCS code? What is the linkage, if any, between coding, payment, and coverage for the product? Researchers and companies need to start early and place the same emphasis on a reimbursement strategy as it does on a regulatory strategy. Your reimbursement strategy staff should be involved early in the process, preferably during product research and development and clinical trial discussions.

INTRODUCTION

CONGRATULATIONS! Your regulatory staff has informed you that your wound care product has been cleared under the particular Food and Drug Administration (FDA) regulation that applies to it. Now, you are ready to commercialize the product in the United States.

The next hurdle is attaining reimbursement for your product, which includes coding, payment, and coverage. Whether your wound care product is a cellular and/or tissue-

based product for wounds (CTP) [previously known as a “skin substitute”], a surgical dressing, negative pressure wound therapy, support surface, or a new technology that does not fit into any of these categories, the reimbursement strategy process should start well in advance of the product launch.

In fact, your reimbursement staff or consultant should be included in conversations beginning with the earliest product research and development discussions and in the design

Information regarding coding, coverage, and payment is provided as a service to our readers. Every effort has been made to ensure the accuracy of the information. Providers, suppliers, and manufacturers are responsible for case-by-case assessment, documentation, and justification of medical necessity. However, Mary Ann Liebert, Inc., and the author do not represent, guarantee, or warranty that the coding, coverage, and payment information is error-free and/or that payment will be received. The ultimate responsibility for verifying coding, coverage, and payment information accuracy lies with the reader.

of the clinical trials. These reimbursement specialists will help your executives and scientists understand the information needed by insurance payers, who are critical to your product's commercial success. They must understand the coding, payment, and coverage processes to establish realistic commercialization time frames and sales goals.

DISCUSSION

What is an HCPCS code?

This article will address the importance of obtaining an appropriate Healthcare Common Procedure Coding System (HCPCS) code (or billing) for your product. While there are two levels of HCPCS codes, it is the Level II codes that manufacturers will be interested in since these will be the ones used to identify their products.

- Level I consists of the Current Procedural Terminology (CPT[®] [registered trademark of the American Medical Association]), an alpha-numeric coding system maintained by the American Medical Association to identify medical services and procedures furnished by physicians and other health care professionals.
- Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes such as drugs and biologicals, or durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) used in outpatient settings such as hospital outpatient departments (HOPD), physicians' offices, and patients' homes.

Currently, Level II HCPCS codes represent ~4,000 separate categories of like items or services that encompass millions of products from different manufacturers. Almost every product used in wound care will need a HCPCS code—this includes surgical dressings, support surfaces, negative pressure wound therapy and its supplies, suction pumps, pneumatic compression devices, CTP, biologics, and drugs. The HCPCS code consists of a single alphabetical letter followed by four numeric digits and contains a generic descriptor that provides the definition of the items that can be billed using that code. The code descriptors use terminology that will include like items into the same code. For example, there are seven HCPCS codes describing hydrogel surgical dressings depending on the size and whether it has an adhesive border. Here is the language for the HCPCS code A6245:

Hydrogel dressing, wound cover, sterile, pad size 16 sq. in. or less, with any size adhesive border, each dressing.

To avoid any appearance of endorsement of a particular product through HCPCS, brand or trade names generally are not used to describe the products represented by a code unless brand distinction is deemed necessary to facilitate compliance with Section 1847A of the Social Security Act (*e.g.*, as it pertains to single-source drugs and biologicals).¹ Therefore, since CPTs are biologicals, they will have their own brand name HCPCS code descriptor.

Coding is distinct from both coverage and payment, but provides essential and universally accepted terminology used in coverage and payment decision-making. These codes are part of a universal code set that is used by all payers: Medicare, Medicaid, and private insurance.

A company must recognize that once it obtains a HCPCS code for its product, the code does not guarantee appropriate coverage or payment for the product—each one of these components must also have a specific strategy developed for them.

Why the correct HCPCS code for your product is essential to a successful reimbursement strategy

The first step to a successful reimbursement strategy is to ensure that your product has the most appropriate HCPCS code. The correct HCPCS code plays an essential role in patient access to new and existing technologies for the following reasons.

- It enables clinicians (providers), manufacturers, and payers to identify with specificity, for billing and claims processing purposes, the product that was furnished to a patient.
- It serves as a means to classify, define, and distinguish a health care product and thus provide a common identifier for clinicians (providers), manufacturers, and payers for obtaining data that measure outcomes and cost.
- For wound care products that are durable medical equipment (DME) and supplies, the HCPCS code descriptor that is assigned to the product has a payment amount (known as a fee schedule) attached to it. It is essential for your product to be placed in a code with other like products. If your product is placed in a HCPCS code that does not include similar products with similar manufacturer's suggested retail price (MSRPs), then the reimbursement established for it by the payer could be inappropriate and thus, not be prescribed or used. For instance, if the retail price for your surgical dressing is \$25.00 and

the HCPCS code that was assigned to your product had a Medicare reimbursement amount of \$17.00, it may be likely that a supplier may choose a different company's product to purchase that is closer to or less than \$17.00. Thus, this HCPCS code may not be appropriate for the product, since the reimbursement rate is not adequate and including it in this code would not allow patient access to your product.

Which regulatory agency issues HCPCS codes?

There are two organizations that issue HCPCS codes:

- The Centers for Medicare & Medicaid Services (CMS), located in Baltimore, Maryland, is the agency that issues new HCPCS codes. CMS uses a HCPCS Workgroup to make its decisions on new codes.
- The Pricing Data Analysis and Coding (PDAC), a CMS contractor in Fargo, North Dakota, has the responsibility to determine the appropriate HCPCS code through a coding verification process. This process is used when a company believes that its product already falls under an existing HCPCS code and needs written verification of it from the PDAC. It is also used by companies who believe that they have a unique product and want verification of that before they would submit an application for a new HCPCS code to CMS.

The company will need to determine whether there is a HCPCS code that already exists, whether its product can be placed in, or whether it is so unique that a new code must be established for it.

CMS may assign either an existing code that describes a similar item or service, a miscellaneous code (*e.g.*, a not elsewhere classified code or a not otherwise specified code), or a new code for payment purposes, whichever is appropriate based upon HCPCS coding criteria as applied to the individual technology.

What factors should a company consider when creating an HCPCS coding strategy?

When devising a strategy to obtain a HCPCS code for its product, companies must consider a number of factors as follows.

1. Has the product gone through the FDA regulatory process or does it need to do so? Will the FDA code designation impact as to which HCPCS code will be assigned to your product?

2. In what site of service do you intend to market your product? Where will your customers use the product? Which coding system (CPT or HCPCS) applies to your product?
3. Does a HCPCS code for a similar product already exist? Does your product fit under the existing HCPCS code?
4. Does your product need a new HCPCS code? What is the linkage, if any, between coding, payment, and coverage for the product?

Each one of these factors is explored below.

Has the product gone through the FDA regulatory process or does it need to do so? Will the FDA code designation impact as to which HCPCS code will be assigned to your product?

This article will assume that the product has been successfully through the required FDA regulatory process. However, when the company is developing its regulatory strategy, it should consider under which FDA product code the FDA will classify your new product. CMS or its contractors may use this information when making coding decisions. For instance, if the company goes through the FDA 510(k) process for its product, it is stating that the product is substantially equivalent to a predicate device. The company should also research what HCPCS code the predicate device has been given in case its product is issued the same HCPCS code. The company should recognize that the FDA 510(k) language may make it difficult to prove a significant difference from the predicate device, unless specific indications justify otherwise. This has happened and does happen: the company must plan accordingly.

In what site of service do you intend to market your product? Where will your customers use the product? Which coding system (CPT or HCPCS) applies to your product?

Wound care products can be used in a variety of settings: hospitals, physicians' offices, HOPDs, patients' homes, skilled nursing facilities, *etc.* It is important to know which settings your company will be targeting with your product. Some settings (*i.e.*, hospitals, skilled nursing facilities) are under a Medicare prospective payment system. In these cases, product costs are typically included in the payment rate and a HCPCS code may not be needed. If the new product targeted toward HOPDs, it might be bundled into a procedure code (CPT) and thus may not need a HCPCS code to identify it. Other product costs, such as CTPs, are separately payable in HOPDs and do require a HCPCS code. If

the company believes its new product will be sold for use by the patient at home, obtaining a HCPCS code will be necessary for the DME supplier to bill for Medicare Part B covered products.

There is one exception to the normal HCPCS code process: transitional pass-through codes for use by HOPDs. The outpatient prospective payment system allows for a temporary (2 or 3 years) pass-through code (known as C codes) to some new products. If the Medicare contractors cover the new product, the C code provides a way for the HOPD to code the product and CMS to pay for it and collect data about the product. This data help Medicare determine how to incorporate payment for the new technology into existing or new HOPD Ambulatory Payment Classification groups.

Does a HCPCS code for a similar product already exist? Does your product fit under the existing HCPCS code?

HCPCS codes for wound care products begin with the following letters:

- A codes: Medical surgical supplies such as surgical dressings.

Example: A6021—Collagen dressing, sterile, pad size 16 sq. in. or less, each

- E codes: DME such as support surfaces or negative pressure wound therapy

Example: E0193—Powered air flotation bed (low air loss therapy)

- Q codes: Biologics such as CTPs [outdated term “skin substitutes”].

Example: Q4124—Oasis Ultra Tri-Layer Wound Matrix, per square centimeter

- C codes: Pass-through code used in HOPDs.

Example: C9363—Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter

The information below is appropriate for those products that would be classified under A or E codes. CTPs have a unique circumstance: since 2009, CMS uses the actual product name to define the code rather than a generic term. Nearly every CTP has its own Q code. However, CMS has recently assigned identical products, which have different brand names, to the same HCPCS Q code.

A company will need to determine if a HCPCS code for its product already exists by perusing the current year’s HCPCS coding book or by researching the HCPCS codes on the CMS website. Even if a company finds that its product may fit under an already existing code, it should consider the following.

Does the code descriptor accurately describe the product? As stated previously, the descriptor is generic except for CTPs and drugs, where it is a brand name, but it is important to ensure that the descriptor does reflect the general technology of your product.

Is a competitive product already assigned to this code? For instance, the company can look on the PDAC website under the DME Coding System (DMECS)² to see which competitive products would be grouped and listed under a particular code. A company that manufactures a negative pressure wound therapy device could list either its product’s name or company or HCPCS code (E2402) in this website and all of the products that have been code verified under this code would be listed. The company would then be able to see which products were in this code thus validating that it would want to code verify its product under this code.

Is the reimbursement rate (known as a fee schedule) adequate for the product? If the answer to any of those questions is no, then the company may want to consider applying for a new HCPCS code.

If the company is satisfied that its product fits well into an already existing HCPCS code, it may want to have its product code verified by the Medicare PDAC. This process is only mandatory if the product is negative pressure wound therapy, Group II support surfaces and a certain category of gradient compression wraps. However, it is common practice for companies to code verify their products for the following reasons.

- Those products that are code verified will appear on the PDAC website under Product Classification Lists. This allows the company’s customers to see that its products are assigned to a particular code and helps for marketing purposes.
- Payers, such as some Medicaid programs, may want to see a PDAC letter from the manufacturer showing that the product falls under a certain code.

The PDAC is located in Fargo, North Dakota, and coding verification applications can be found on their website.³ The company will need to figure out which type of product it has and submit the particular type of coding verification application for it. For instance, there are distinct applications for surgical dressings and support surfaces. If your product is considered DME, such as negative

pressure wound therapy or a pneumatic compression device, you would use a DME application.

Within 90 days of receiving the application, the PDAC will provide a letter to the manufacturer stating the HCPCS code under which the contractor believes it should be billed. It is usually the code for which the manufacturer has submitted. If it is not, the company can submit a reconsideration form and speak to the PDAC clinical staff. In addition, the PDAC will meet with manufacturers before a coding verification is submitted, if the company wants to educate the contractor on its product. This process is usually a relatively quick and easy one for the manufacturer.

Does your product need a new HCPCS code? What is the linkage, if any, between coding, payment, and coverage for the product?

If the company determines that a HCPCS code does not exist for its product and customers do not want to bill it with a miscellaneous HCPCS code, then the company should pursue obtaining a new HCPCS code.

For new CTPs, this has been a very straightforward pathway. A company completes the HCPCS code application and, for the most part, the CMS HCPCS Workgroup issues a brand-specific code for the CTP. As noted above, however, CMS has recently assigned identical products, which have different brand names, to the same HCPCS Q code.

However, for new DME and supplies, the CMS HCPCS coding process has not been transparent, understandable, or predictable. Both the number of applications submitted and the number of new HCPCS codes assigned to DMEPOS by the CMS HCPCS Workgroup have dramatically decreased over the years. Each year, there are typically 10–15 or less new HCPCS codes issued by CMS. In fact, unless the company believes it has a breakthrough technology, many manufacturers have chosen not to navigate through the new HCPCS coding process. Instead, they put their resources elsewhere and simply try to place their product in an existing HCPCS code by submitting a coding verification application.

If the company wants to submit for a new HCPCS code, these are the issues that should be considered, especially when developing the company's reimbursement strategy.

Timing. HCPCS code applications are accepted throughout the year, but the deadline for each year is the first week in January (in 2013, it was January 4th). The CMS HCPCS Workgroup makes preliminary coding decisions in April/May and

there is a HCPCS public meeting, during which the applicant or its designated representative can make a 15-min presentation if it did not receive the code it requested. The final HCPCS codes are released in mid-November and take effect in January of the next calendar year. Currently, there is no HCPCS code reconsideration or appeal process. If CMS did not award the requested code, the company should reapply by the next January deadline.

Accessing the HCPCS code application. The HCPCS code application can be found on the CMS website.⁴

By completing this, the company can ask to establish, revise, or discontinue a HCPCS code via the HCPCS code application.

As stated earlier in this article, when the company establishes its reimbursement strategy, it is essential for the company to review the HCPCS coding application and the criteria used by the HCPCS Workgroup to establish a new HCPCS. The decision tree and definitions that CMS uses are available online.⁵

By doing this, the company will understand the criteria it will need to collect (as noted below) way in advance of submitting the application to CMS. For example, when the company does its studies for the FDA, it might be able to use the same study, but include additional criteria to satisfy CMS's choice of endpoints.

Collecting data

Information that the company will need to plan ahead to collect so as to include in the application:

Clinical studies to demonstrate how the product results in a significantly improved medical outcome or significantly superior clinical outcome. This is one of the key questions in the HCPCS code application. CMS will ask the company to articulate the clinical therapy behind the claim of significant therapeutic distinction, including differences in the product or its operation as it compares to currently coded products. CMS will also ask the company to provide the best available information related to the product's claim and to include copies of all published articles that result from the company's systematic analysis of the available literature and any unfavorable published articles with any appropriate rebuttal or explanation.

CMS will request the highest level of scientific evidence such as randomized controlled clinical trials, but will accept other types of studies as long as they are published in peer-reviewed journals.

The HCPCS Workgroup prefers U.S. based journals and often asks for trials that are performed on Medicare qualified patients, even though the HCPCS code set is for all payers.

Historically, CMS's request for this high level of evidence has been associated with obtaining coverage, not coding. Traditionally, CMS has used criteria such as significant technological differences, significant clinical indications, and different patient populations to establish a code. Unfortunately, there has been a trend over the past 10 years for CMS and its HCPCS Workgroup to commingle coverage criteria with coding criteria in its HCPCS coding process. Its coding determinations often include the review of clinical evidence similar to the information used to determine coverage policies. This approach overlooks the fact that HCPCS codes are used by numerous health plans nationwide; these plans may have coverage and payment policies that are different from Medicare as well as member demographics that differ markedly from the Medicare population. This approach also overlooks the fact that under the Medicare program and many nongovernmental health plans, coverage, coding, and payment are distinct functions that use different standards. Thus, the company should be aware that by CMS tying together coding criteria with coverage criteria for a new code to be established for a product may undermine other payers' ability (such as state Medicaid agencies and private insurance), to establish their own coverage policies around technologies that they believe best meets the needs of their enrollees.

Sales. For DMEPOS HCPCS code applications, there must be at least 3 months of sales following the FDA approval date. The company will also need to state for the 3 months before submitting the code application, the total number of units sold in the U.S., and the total dollar amount in sales broken down by Medicare, Medicaid, and private insurance. For those companies who manufacture CTPs, only the date of the first sale is required, rather than any information regarding the number of units sold.

This question is asked to ensure that there are enough sales of the product that a new HCPCS code is warranted versus the CMS HCPCS Workgroup issuing it a miscellaneous code or placing it in an already existing code.

MSRP or list price of the item. The company will again need to be aware that this question is asked on the application and must plan ahead to

establish the MSRP for the product as it develops plans for the product launch.

Does the product qualify under a Medicare defined benefit category? Another requirement in the HCPCS code application is to select the HCPCS category that most accurately describes the item, such as surgical dressing, drug/biological, or DME. For a product to be covered under the Medicare program, it must fit into one of these Medicare covered benefit categories. This is one of the ways by which the company must think about the linkage between coding, coverage, and payment.

For instance, one trend for wound care manufacturers is in creating disposable products. Currently, the Medicare program does not have a defined benefit category for disposable products. Therefore, disposable products may not be covered or reimbursed under Medicare. When companies manufacture disposable products, they should develop a marketing and sales strategy that will target sites of care, where disposables are bundled into their Medicare payment rate.

To clarify its noncoverage of disposable products, CMS recently changed its definition for DME. There are now questions on the HCPCS code application that request the length of time that the product can withstand repeated use, its warranty, and if the product is disposable or has disposable components.

CONCLUSION

After reading the article, many might question whether it is worth the effort to try to obtain a new HCPCS code. Appropriate HCPCS codes are important when launching new technology into the marketplace. Researchers and companies need to start early and place the same emphasis on a reimbursement strategy as it does on a regulatory strategy. Involve your reimbursement strategy staff early in the process, preferably during product research and development and clinical trial discussions.

ACKNOWLEDGMENTS AND FUNDING SOURCES

No grant support or funding sources were provided for this manuscript.

AUTHOR DISCLOSURE AND GHOSTWRITING

No competing financial interests exist. The content of this article was expressly written by the author listed. No ghostwriters were used to write this article.

ABOUT THE AUTHOR

Marcia Nusgart, RPh, is the Executive Director of the Alliance of Wound Care Stakeholders, a nonprofit interprofessional association of health care professionals and patient organizations that address regulatory and legislative issues impacting wound care. She also serves as the Executive Director for the Coalition of Wound Care Manufacturers and President of Nusgart Consulting LLC.

As executive director of the Alliance, she organized its efforts in writing a manuscript, published in May/June 2012, *Wound Repair and Regeneration* defining a set of principles providing direction to stakeholders involved in clinical research in

wound healing as well as commenting on Medicare coverage policies impacting wound care.

She is an industry leader in providing comprehensive strategies to medical device manufacturers regarding coding, coverage, and reimbursement issues under Medicare and Medicaid. Her accomplishments range from advocating successfully, in her coalition capacity, for the CMS to modernize the HCPCS coding process to make it more timely, transparent, and understandable for manufacturers to, in her consulting role, obtaining new HCPCS codes along with appropriate coverage and payment for manufacturers' products. Ms. Nusgart is also well known in the wound care industry through speaking engagements at national conferences.

REFERENCES

1. U.S. Social Security Administration: Use of Average Sales Price Payment Methodology. Sec. 1847A [42 U.S.C. 1395w-3a]. www.ssa.gov/OP_Home/ssact/title18/1847A.htm
2. Noridian Health Solutions: Pricing Data Analysis and Coding Contractor website. www.dmeptac.com/dmecsapp/do/search (accessed May 31, 2013).
3. Noridian Health Solutions: Pricing Data Analysis and Coding Contractor website. www.dmeptac.com/review/apps_check.html (accessed May 31, 2013).
4. Centers for Medicare & Medicaid Services website. www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2014_HCPCS_Application.pdf (accessed May 31, 2013).
5. Centers for Medicare and Medicaid Services website. www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCS_Decision_Tree_and_Definitions.pdf (accessed May 31, 2013).

Abbreviations and Acronyms

CMS = Centers for Medicare & Medicaid Services
CPT® = Common Procedure Terminology

CTP = cellular and/or tissue-based products for wounds
DME = durable medical equipment
DMECS = Durable Medical Equipment Coding System
DMEPOS = durable medical equipment prosthetic and orthotic supplies
FDA = Food and Drug Administration
HCPCS = Healthcare Common Procedure Coding System
HOPD = hospital outpatient department
MSRP = manufacturer's suggested retail price
PDAC = Pricing Data Analysis and Coding