

It Takes a Team to Obtain Reimbursement!

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Wound care manufacturers, hospital outpatient wound care provider-based departments, physicians, and other qualified health care professionals often underestimate the time and energy that should be devoted toward the components of reimbursement (coding, payment, and coverage) that pertain to their technology and their businesses. In addition, they often attempt to leap the reimbursement hurdles by themselves. This article (1) describes the value of using a team to obtain adequate and correct reimbursement and (2) emphasizes the wisdom of engaging reimbursement strategy experts, key opinion leaders, professional medical specialty societies, Medical Advisory Boards, and revenue cycle personnel early in the development cycle of new products and in the creation of outpatient wound care businesses.

Keywords: reimbursement, wound care business, coverage, coding, payment

INTRODUCTION

NOT A WEEK GOES BY without this author receiving calls from wound care stakeholders asking questions such as the following:

Manufacturers: “We just received our Food and Drug Administration (FDA) marketing clearance. The wound care physicians say they cannot use the new product because it does not have a Healthcare Procedure Coding System (HCPCS) code or Current Procedural Terminology (CPT®* code). Will you please tell us how to quickly obtain a code?”

Hospital Outpatient Wound Care Provider-Based Departments (PBDs): “Our PBD has been in existence for 5 years. We have been coding and billing the same way for 5 years and have been paid by Medicare for most of our work. We recently had a Medicare audit and incurred a very large repayment. We do not understand what

we did wrong. Will you please educate us?”

Physicians and Other Qualified Healthcare Professionals (QHPs): “I have been providing wound care services in a hospital outpatient wound care PBD for the past 8 years. I recently had a Medicare audit and incurred a very large repayment. I do not understand what I did wrong. I coded and billed just like my peers who work in a similar PBD. All of us have been previously paid for our work by Medicare. Will you please educate me on how to prevent this from happening again?”

This article addresses how to prevent these situations and provides high-level checklists that manufacturers and wound care providers and professionals can use when working with wound care reimbursement strategy consultants, key opinion leaders, professional medical societies, Medical Advisory Boards, and revenue cycle personnel to design their wound care reimbursement strategy and revenue cycle process.



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*CPT is a registered trademark of the American Medical Association.

DISCUSSION

Manufacturers

Manufacturers and their scientists could save a large amount of wasted time and money if they engaged a reimbursement strategy expert (company employee or consultant) when the idea for a new technology is “drawn on a paper napkin.” Too often manufacturers and scientists are so excited about developing their new technology and about focusing on obtaining marketing clearance/approval from the FDA that they fail to consider creating a reimbursement strategy. They do not understand that an FDA marketing clearance does not equal reimbursement. In fact, after a new technology receives FDA marketing clearance/approval, payers often say, “So the product is safe and effective, why should we pay for it rather than other products that cost less?”

Manufacturers often underestimate how the lack of reimbursement can hinder, and sometimes sink, a successful product launch. They also underestimate the amount of time, money, and people needed to gain the three components of reimbursement: codes, coverage, and payment. Just like it takes a team to develop a product and to obtain FDA marketing clearance/approval, it takes a team to obtain the three components of reimbursement. The reimbursement team must begin working with the product development team and the FDA application team when the product is simply an “idea.”

The special December 2013 wound care reimbursement issue of *Advances in Wound Care*¹ reviewed the following:

- The need for appropriate International Classification of Diseases, 10th Edition, Clinical Modification (ICD-10-CM) diagnosis codes or International Classification of Diseases, 10th Edition, Procedure Coding System (ICD-10-PCS) procedure codes to describe the medical necessity for new technology.
- Why and how CPT codes are developed for procedures affiliated with new technology?
- Why obtaining a HCPCS code, if needed, should be a part of the reimbursement strategy?
- The role of health economics information in wound care.
- The role of volume-based and value-based payment systems.
- The need to work with payers to gain coverage.
- The use of specialty registries for data collection.
- Medicare resources that are available to assist wound care manufacturers.

In this November 2018 special wound care reimbursement issue:

- Donna Cartwright (page 354) emphasizes how company-employed coding specialists or coding consultants, along with an appropriate professional medical specialty society, should be included on the product development team to identify if a new ICD-10-CM or ICD-10-PCS code² is needed and to lead the application process for a new code when needed.
- Marcia Nusgart (page 358) provides tips for navigating the HCPCS process and highly recommends using (1) experienced consultants to prepare the HCPCS code application³ and (2) a key opinion leader such as a physician/clinician who can speak passionately, but objectively, at the HCPCS public meeting when the new product’s application is reviewed.
- Dr. Garoufalis (page 363) explains how the road to gaining a new CPT code⁴ is long and can be filled with “potholes.” He encourages readers to build a CPT code team composed of key opinion leaders and their professional medical specialty societies, Medical Advisory Boards, and the CPT Editorial Panel staff when a new CPT code is needed.
- Dr. Carter’s article about illustrating the differences in the cost-to-heal wounds using two methods: (1) reimbursement-based costing and (2) activity-based costing (ABC), and (page 371) highlights why health economists should be consulted to assist with clinical trial design.
- Dr. Gillian (page 380) provides an overview of comparative effectiveness research (CER) methodology and emphasizes the need to consider health economics and outcomes research (HEOR) before designing clinical trials and determining how data will be collected.
- Dr. Drucek (page 367) discusses the need to work with professional medical societies and organizations to develop wound care clinical practice guidelines and standards that not only guide patient care but are also used by payers to make coverage⁵ and payment decisions about new wound care technology.
- Dr. Fife *et al.* (page 387) explains how data collected in specialty registries⁶ can be used for CER.

Following is a high-level checklist that manufacturers should use to assemble the reimbursement team who will develop the reimbursement strategy in a parallel path with the regulatory

team who will develop the FDA market clearance strategy. Manufacturers' internal and external team members should develop the strategy and time line for each of these major stepping stones to reimbursement success.

- ✓ Determine if appropriate ICD-10-CM/ICS-10-PCS codes exist and apply for new ones if needed to specify medical necessity for the new technology.
- ✓ Determine if a HCPCS code exists that describes the new technology and apply for a new HCPCS code if needed (draft a sample HCPCS code application early in the development of the product to gain an appreciation of the clinical evidence that will be needed).
- ✓ Identify if a CPT code exists that describes the procedure (if any) affiliated with the new technology and apply for a new CPT code if needed.
- ✓ Consider collecting health economic data simultaneously to clinical data in clinical trials: consider using wound care-qualified clinical data registries (QCDRs).
- ✓ Review existing and draft clinical practice guidelines and standards and work with the various organizations to be sure the terminology in the published documents is inclusive of the new technology.
- ✓ Review pertinent payers' coverage policies and work to refine them if they do not provide coverage for products/procedures that have published clinical evidence.

Hospital Outpatient Wound Care PBDs

When hospitals decide to open a hospital outpatient wound care PBD, they tend to focus on creating the space for the department. Then, they usually look for a wound care-certified nurse or therapist to direct the operations of the department. That certification ensures they can oversee the actual wound care provided in the department, but it does not necessarily ensure they are prepared to direct the business side of the department. In addition, the appointed director is often notified of his/her new position a few weeks before the PBD is scheduled to open and is still required to continue the work of his/her current position until the PBD opening day: he/she is not usually given education on how to work with the entire revenue cycle team and is not given adequate time to establish processes that align with reimbursement regulations. Therefore, these resourceful wound care specialists tend to contact their peers who are directing noncompeting PBDs, which are often in different states: they assume their peers are com-

pliantly following regulations and fail to realize that their peers were most likely thrown into their positions without proper training.

Hospitals could save a lot of time and money if they (1) named the PBD program director about 6 months before they opened the wound care department, (2) released the program director from his/her current position to establish the clinical and business processes of the new department and to work with reimbursement consultants who specialize in the operation of wound care departments, (3) gave the program director time to read the regulations and journal articles pertaining to PBDs paid by the Medicare Outpatient Prospective Payment System (OPPS),⁷ and (4) trained the program director on how to work with all the departments in the revenue cycle.

The articles in the special December 2013 wound care reimbursement issue and this special November 2018 issue of *Advances in Wound Care* provide invaluable information for program directors. Because both the PBD and the physicians who work there are now required to (1) focus on providing quality (not just quantity) care with excellent outcomes, (2) document medical care via interoperable systems, (3) achieve excellent patient satisfaction, and (4) reduce the total cost of care, program directors should build the use of reporting data through wound care-specific registries into their operating processes (article by Dr. Fife *et al.* on page 387).

Some hospitals may choose to turn the operation of a PBD over to a wound management company, while other hospitals may choose to manage the PBD internally. If the hospital decides to manage the PBD internally (which is entirely possible), the hospital and newly appointed program director should work with all members of the revenue cycle team and should seek an outside reimbursement consultant to assist them with understanding and implementing OPSS regulations, developing their charge description master (CDM), and so on: the dollars spent in the front end will save huge repayments in the back end!

Following is a high-level checklist that hospitals (along with their reimbursement consultant) should use to launch a new outpatient wound care PBD or to improve a PBD that continues to be audited:

- ✓ Select a wound care-specific electronic health record.
- ✓ Select a wound care-specific QCDR.
- ✓ Identify the medical director, physicians and other QHPs, wound care nurses and therapists, along with the exact services, procedures, and products they will provide to patients.
- ✓ Identify (1) codes and coding rules, (2) payment and payment rules, and (3) pertinent

payers' coverage policies that are affiliated with the services, procedures, and products; train all the medical professionals and revenue cycle team members about these unique rules and policies.

- ✔ Create a unique CDM that accurately reflects the work, products, and accurate charges of the PBD.
- ✔ Build the business policies and procedures (P&Ps), for example, clinic visit mapping tool, direct supervision of P&P, responsibility for attaching modifiers to codes, and self-auditing process that begins when the PBD opens and continues monthly.
- ✔ Establish a revenue cycle that supports the unique needs of the outpatient wound care PBD, for example, episodic (not monthly) billing, correct calculation of units for all procedures and products, coding for all work performed, correct use of modifiers, correct coding when clinic visits and procedures are performed at the same visit, review of remittance advice, and review of revenue collected versus charges.
- ✔ Provide the resources (including reimbursement information published by their wound care organizations) and venue for ongoing wound care-specific reimbursement education for the wound care professionals, management team, and pertinent revenue cycle stakeholders.

Physicians and Other QHPs

Like hospitals, physicians and other QHPs often decide to provide wound care in their offices, in hospital outpatient wound care PBDs, in skilled nursing homes, and so on, without establishing the processes and P&Ps necessary to support these unique services, procedures, and products. They mistakenly believe that the wound care regulations and rules are the same as other types of procedures and products and are the same in all sites of care. Worse yet, they tend to seek reimbursement information from their peers rather than from wound care coding, payment, and coverage specialists. Basing their wound care business on inaccurate reimbursement information is the main reason physicians and other QHPs often face repayment situations.

The reimbursement information in both the December 2013 issue and this November 2018 issue of *Advances in Wound Care* contains a plethora of information that should prove helpful to physicians and other QHPs. In addition, physicians and other QHPs who perform or wish to perform wound care should enlist the guidance of a reimbursement consultant who understands the nuances of the unique coding, payment, and coverage regulations/

rules pertinent to the work they wish to perform and to the site(s) of care where they wish to work.

Following is a high-level checklist that physicians and other QHPs (along with their reimbursement consultant) should use when deciding to provide wound care services or to improve their processes when they continue to be audited:

- Select a wound care-specific electronic health record.
- Select a wound care-specific QCDR.
- Identify the physicians, other QHPs, wound care nurses and therapists who will perform the work, along with the exact services, procedures, and products they will provide, and the sites of care where the work will be performed.
- Identify (1) codes and coding rules, (2) payment and payment rules,⁸ and (3) pertinent payers' coverage policies that are affiliated with the services, procedures, and products in the various sites of care; train all the medical professionals and revenue cycle team members about these unique rules and policies.
- Create a unique charging and billing system that accurately reflects the work, products, and accurate charges in the various sites of care.
- Build the business P&Ps, for example, incident to coding and billing, responsibility for attaching modifiers to codes, and self-auditing process that begins when the PBD opens and continues monthly.
- Establish a revenue cycle that supports the unique wound care coding and billing regulations and rules, for example, new and established evaluation and management (E&M) visits, correct calculation of units for all procedures and products, coding for all work performed, correct use of modifiers, correct coding when clinic visits and procedures are performed at the same visit, review of remittance advice, and review of revenue collected versus charges.
- Provide the resources⁹ (including reimbursement information published by their professional medical societies) and venue for ongoing wound care-specific reimbursement education for the wound care professionals, management team, and pertinent revenue cycle stakeholders.

DISCLAIMER

Information regarding coding, coverage, and payment is provided as a service to our readers. Every effort has been made to ensure accuracy of information. Providers, suppliers, and manufac-

turers 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.

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TAKE-HOME MESSAGES

- Outpatient wound care coding, coverage, and payment regulations and rules are unique from inpatient regulations/rules for similar services.
- Wound care-certified professionals receive little, if any, training in outpatient wound care reimbursement regulations/rules.
- Hospitals, physicians, and other QHPs should enlist the assistance of wound care reimbursement consultants, key opinion leaders, professional medical societies, Medical Advisory Boards, as well as the entire revenue cycle team.
- Wound care professionals should read pertinent wound care reimbursement journal articles and should attend pertinent wound care reimbursement education programs to learn current regulations and rules (which can change frequently).

son Medical (Director of Reimbursement), and Bimeco (Manager of Alternate Care Sales Division). Kathleen has consulted with hundreds of wound care departments and physicians to start new wound care programs or to transform existing programs that were previously in disarray. She has developed the reimbursement strategy for numerous wound care device/biologic manufacturers. In addition to founding and presenting at 10 Wound Clinic Business¹⁰ seminars per year, Kathleen provides reimbursement education at many regional and national wound care symposiums, as well as for many wound care manufacturers' executives and sales representatives. As a writer and authority in her field, Kathleen has a running monthly column in two medical journals: *Payment Strategies in Advances in Skin & Wound Care*⁹ and *Business Briefs in Today's Wound Clinic*.¹¹ She also serves on the editorial boards of *Today's Wound Clinic and Wound Source*.

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Abbreviations and Acronyms

CDM	= charge description master
CER	= comparative effectiveness research
CPT [®]	= Current Procedural Terminology
FDA	= Food and Drug Administration
HCPCS	= Healthcare Procedure Coding System
ICD-10-CM	= International Classification of Diseases, 10th Edition, Clinical Modification
ICD-10-PCS	= International Classification of Diseases, 10th Edition, Procedure Coding System
OPPS	= Outpatient Prospective Payment System
P&Ps	= policies and procedures
PBD	= Provider-Based Department
QCDRs	= qualified clinical data registries
QHP	= qualified healthcare professional