Include Payers in Your Product Development and Clinical Use Processes

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Wound/ulcer management scientists, researchers, manufacturers, professionals, and providers cannot assume that clearance or approval by the Food and Drug Administration (FDA) will guarantee reimbursement for medical devices they develop or wish to use in their practices. Even if a relative code and a published payment rate for the code exist, if the payers do not provide coverage for the technology, the devices may not be able to be sold and used in all settings throughout the continuum of care. Unfortunately, reimbursement (particularly coverage) is often an after-thought once FDA clearance or approval is achieved. This article describes two new Medicare coverage processes that should encourage all stakeholders to educate payers early and often why important medical devices should be covered for their patients with wounds/ulcers.

Keywords: reimbursement, wound care business, coverage, coding, payment, Centers for Medicare and Medicaid Services

INTRODUCTION

FOR MORE THAN 20 YEARS, this author and reimbursement strategy consultant has been assisting scientists, researchers, manufacturers, and wound/ulcer management providers and professionals to gain codes, payment, and coverage for new medical devices. Unfortunately, most of that assistance happened after the work with the Food and Drug Administration (FDA) was completed and the stakeholders realized they could not easily sell or use the new technology because a reimbursement strategy was not planned in tandem with the FDA strategy. For some unknown reason, many stakeholders do not include payers in their product development and clinical use processes.

Even though *Advances in Wound Care* is a research-based clinical journal, the editor recognizes the importance of reimbursement and

has periodically published reimbursement articles in the journal. You may recall that *Advances in Wound Care* was first published as a two-volume book. In volume 2, which was published in 2011, Section 11 Reimbursement Updates included an article¹ that educated readers how the following coverage processes impact sales and clinical use of new and existing technology: National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and closed Contractor Advisory Committee (CAC) meetings. That article is still pertinent today.

When reimbursement issues continued to plague the wound/ulcer management industry, the entire December 2013 issue of this journal was dedicated to reimbursement-related topics. All of the articles in that issue are still relevant today. One of the articles² educated stakeholders about the Medicare Coverage

Database, about the specific information included in LCDs, how to monitor changes in NCDs and LCDs, and how to exercise your right to comment on and challenge LCDs. Another article³ provided easily accessed Medicare coding, payment, and coverage information that all stakeholders should use from the time the idea for a product “is drawn on a napkin” to product launch, and throughout the life cycle of the product.

Five years later when the industry still seemed to be confused about including reimbursement strategies in medical device development and clinical use processes, the entire November 2018 issue of this journal covered additional reimbursement-related topics. All of the articles in that issue are still relevant today. One of the articles⁴ provided checklists that stakeholders (*e.g.*, manufacturers, hospital outpatient wound/ulcer management provider-based departments, and physicians) can use to design their reimbursement strategy and revenue cycle process.

If you have not read these 2013 and 2018 reimbursement themed issues, this author highly recommends that you do so. They are timeless references that should be used on an ongoing basis.

As the new decade begins, one might think that the wound/ulcer management stakeholders have heard the reimbursement strategy messages enough that implementing them would be “second nature” to all. Unfortunately, several times a month this author and many other reimbursement strategy colleagues receive calls from (1) scientists, researchers, and manufacturers who failed to include a reimbursement strategy into their product development plan, and (2) wound/ulcer management professionals and providers who purchased new technology and did not receive payment for it because either their documentation did not align with coverage guidelines or the product was not covered. Therefore, this article is intended to provide some new coverage information that will encourage wound/ulcer management stakeholders to include payers into their medical device development and clinical use processes. Please note that the coverage for certain products, such as (1) prescription drugs that are either bundled into provider payments or are part of the drug formulary process and (2) equipment, software, and devices that are bundled into provider payments, are not in the scope of this article.

DISCUSSION

New Local Coverage Determination process

No matter whether you are a researcher, a scientist, a manufacturer, or a wound/ulcer manage-

ment professional or provider, you must consider whether the technology you are developing or using is covered by Medicare. For example: When manufacturers (1) released cellular and/or tissue-based products (CTPs) for skin wounds that were either micronized particles or liquids/gels and (2) were assigned a Healthcare Procedure Coding System code for the products, they and the wound/ulcer management professionals/providers were surprised to learn that Medicare does not cover CTPs that are not sheets.

Many stakeholders still do not know that LCDs exist. Many other stakeholders reported that they did not provide comments to draft LCDs because (1) the LCD process was not transparent, (2) that the Medicare Administrative Contractors (MACs) did not provide adequate time to prepare for participation in public LCD meetings, and (3) that the Contractor Advisory Committee (CAC) members were never publicly divulged and their meetings that discussed draft LCDs were closed to the public. Following is some good news that should encourage all stakeholders to participate in the coverage process.

Effective January 8, 2019, the Centers for Medicare & Medicaid Services (CMS) implemented a new transparent LCD process that provides more opportunities for all stakeholders to participate. In fact, interested parties (*e.g.*, beneficiaries, health care professionals, and people doing business in the MAC’s jurisdiction) can now request informal meetings with the MAC to discuss potential LCD requests, and can use the new LCD request process to request creation of a new LCD. When an MAC proposes a new LCD or proposes coverage changes to an existing LCD, the MAC must now follow these steps that makes the process more transparent:

- Consult with experts on the topic of the proposed LCD.
 - The CAC meetings are now open to the public and the CAC participants include a variety of health care professionals as well as beneficiaries.
- Publish a standardized summary of clinical evidence that supports their proposed LCD and that includes:
 - Complete description of the item or service.
 - Narrative that describes the scientific evidence supporting the clinical indications for the item or services. The MAC shall use the available evidence of general acceptance by the medical community, such as

published original research in peer-reviewed medical journals, systematic reviews, meta-analyses, evidence-based consensus statements, and clinical guidelines.

- Target Medicare populations.
- Intended use by health care professionals or by beneficiaries.
- United States FDA labeling requirements for use of the item or service, whether it is regulated by the FDA and determined by the MAC to be reasonable and necessary.
- Conduct an open LCD meeting that is announced a minimum of 2 weeks before the meeting.
 - The purpose of the meeting is for the MAC to present the proposed LCD, their review of the evidence, and their rationale for the proposed LCD.
- Provide a public comment period (minimum of 45 calendar days) for all proposed LCDs.
- Publish the final LCD as well as a response to comments received from the public.
 - LCDs may no longer contain any coding information. The MACs were required to remove all codes from existing LCDs and were required to place the codes in billing and coding articles.
 - If it is appropriate for a MAC to provide coding and billing information to help implement a new LCD, the MAC shall publish a coding and billing article at the same time it publishes the proposed LCD.
- Provide a public notice of the final LCD 45 days in advance of the effective date.

As you can see, this new LCD process provides many opportunities for all stakeholders to discuss coverage issues with the MACs, to educate them, and to influence coverage determinations for technology that support excellent patient outcomes. Wound/ulcer management stakeholders should take full advantage of this new LCD process. For example: When wound/ulcer management professionals adopt new technology that helps them diagnose and/or treat their patients', they may experience inconsistent claims processing by their MAC. That may be a great time to request an informal meeting with their MAC (1) to educate them about the benefits of the new technology and (2) to discuss a potential new LCD. If the MAC agrees to write a pertinent new LCD, the MAC medical director(s) will start with a clear understanding of the new technology.

New LCD Reconsideration process

Even though an LCD Reconsideration process has existed for many years, very few stakeholders used it to educate payers when new evidence was available that could change LCDs. When asked "why don't you submit an LCD Reconsideration request if you have clinical evidence that the LCD may no longer be correct?" most stakeholders replied that "the LCD Reconsideration process is vague and probably not worth the effort."

All stakeholders should celebrate that the CMS also implemented a new LCD Reconsideration process on January 8, 2019. Now each MAC is required to include the LCD Reconsideration process instructions on the LCD home page of its website. Each MAC must follow the full LCD process for valid LCD Reconsideration requests, and shall determine whether the request is valid or invalid within 60 calendar days of receiving it.

Wound/ulcer management stakeholders should use the new LCD Reconsideration process to educate the payers when LCDs are outdated and/or incorrect. Because the MACs are responsible for making coverage decisions and processing claims for all services, products, and procedures performed and used in their jurisdiction, they may not know new published evidence that could change an LCD, unless wound/ulcer management stakeholders educate them through an LCD Reconsideration request. For example: If wound/ulcer management stakeholders know about new published evidence that could possibly turn negative coverage into positive coverage for a specific product, or have evidence that utilization guidelines need to be revised, they should consider educating their MAC through the new LCD Reconsideration process.

SUMMARY

For at least 30 years, reimbursement consultants have been encouraging wound/ulcer management manufacturers to consider, while the idea for a new product is in the drawing stage, whether the product will be covered. Unfortunately, manufacturers often focus on getting through the FDA as quickly as possible and often make mistakes in their FDA submission that prevent them from obtaining coverage for reimbursement. Once medical devices are FDA cleared or approved, the payers must decide whether they will cover the technology for payment. No matter whether you are a researcher, a scientist, a manufacturer, a medical professional, or a medical provider, you must pay attention to the payers' current coverage decisions. You must take an active role in educating the

payers why covering the technology you wish to sell/use will benefit the clinical outcomes for their patients, will reduce the total cost of care, and will improve the patients' satisfaction.

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TAKE-HOME MESSAGES

- When developing new technology, researchers, scientists, and manufacturers should develop a reimbursement strategy simultaneously to developing an FDA strategy.
- When launching or using new technology, the existence of a code and a published rate for the code are only two pieces of the three-piece reimbursement puzzle: positive coverage is the third essential piece.
- Throughout the new technology development process, the stakeholders should monitor and comment on coverage determinations that might affect the new technology in the future, and should take time to educate the payers about the technology before the product is launched and before coverage is requested.
- Medical professionals, providers, and beneficiaries should monitor changes to LCDs and coding and billing articles and should incorporate them into their documentation and medical decision making.
- All stakeholders should participate in the new public comment opportunities for proposed LCDs and should use the new LCD Reconsideration process when new clinical evidence is available that could change the MAC's coverage determination.

seminars per year, Kathleen provides reimbursement education at many regional/national symposiums, as well as for many manufacturers' executives and sales representatives. Kathleen has a monthly column in two medical journals: *Payment Strategies* in *Advances in Skin & Wound Care* and *Business Briefs* in *Today's Wound Clinic*. She also serves on the editorial boards of *Today's Wound Clinic* and *Wound Source*. Kathleen was recently identified by *expertscape* as a world expert for health care reimbursement publishing: she is in the top 0.051% of 29,342 published authors worldwide from 2010 through 2020.

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Abbreviations and Acronyms

CAC = Contractor Advisory Committee
 CMS = Centers for Medicare & Medicaid Services
 CTP = cellular and/or tissue-based product
 FDA = Food and Drug Administration
 LCD = Local Coverage Determination
 MAC = Medicare Administrative Contractor
 NCD = National Coverage Determination