

Coverage, Coding, and Payment: 3 Considerations for Successful Reimbursement in Clinical Trials

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Mary Kay Kessinger Sobcinski, MHA, RN, Senior Director, Strategic Consulting

Jennifer Varela, Senior Manager, Reimbursement

"I thought FDA approval was all I needed." This is a common refrain among medical device executives who fail to proactively design their clinical trials to gather critical reimbursement information. They are unpleasantly surprised to learn that while the FDA has greenlit the selling of their product, no one is willing to buy it until Medicare and private payers agree on the terms of repayment. Failure to incorporate reimbursement strategy into a trial's design means it won't collect the necessary data to support publications and effectively seek restitution in the long term, resulting in lost revenue, shrinking market share, and untold headaches for the sponsor. In fact, Avania has a history of filling in the gaps post-approval by gathering the missing health economics and reimbursement data not collected during these same regulatory approval trials. That said, while CRO assistance can be precise and comprehensive, this retroactive approach is time-consuming, expensive, frustrating, and ultimately may be unnecessary.

MedTech companies typically design their trials with three objectives in mind: (1) obtaining evidence of safety and effectiveness, (2) obtaining regulatory approval, and (3) supporting market launch claims with robust data. However, establishing and executing a reimbursement strategy is just as important, though it is often neglected early in the trial design process. In this sense, proactive planning that considers coverage, coding, and payment means not only will you have approval to sell your MedTech innovation, but someone will be ready to pay for it.

That said, healthcare reimbursement in the United States is one of the most complicated systems in the world. Consequently, developing an effective reimbursement strategy can be daunting and complex. When confronted with a task that is both critical to the success of your medical device and challenging to accomplish, it is imperative to understand every step and consult a reimbursement strategist early in trial development. This will ensure all necessary data points are collected to satisfy the three major considerations of successful reimbursement strategy: device coverage, coding, and payment.

1. Coverage

"Coverage" refers to the terms and conditions under which the Centers for Medicare and Medicaid Services (CMS) and private payers will issue payment for medical devices and their associated surgical procedures. It can be critical to obtain a favorable decision from the very beginning, as the initial CMS decision will often set the tone for what is to follow. Early Medicare approval can pave the way for

other payers to follow suit, while initial CMS denial means private and commercial payers will likely also deny coverage.

Medicare makes coverage decisions for specific products by analyzing the effectiveness and health outcomes data gathered during the clinical trials in question (see sidebar). Upon review, Medicare must be assured that the new technology will substantially improve patients' health outcomes above and beyond established treatments.

Reimbursement-related data analysis typically consists of comparisons between the treatment (investigational device) group with the control (standard of care) group. Common data points include length of stay (LOS), intensive care unit (ICU) admittance, readmission after discharge, prolonged use of medications outside of standard of care, occurrence of adverse events, and procedure time. Additional data points may be helpful depending on the technology and condition under investigation. In addition to incorporating these and other related data points into the investigational plan (protocol), it is wise to have the study biostatistician review these items to ensure they are worded for optimal analysis and that the correct wording is used in both the investigational plan and case report forms. Finally, it is important to incorporate the collection of health economic and reimbursement data into the informed consent form to assure the subjects are aware that these data are being collected and anonymously reported to CMS and private payers.



It is essential to understand that Medicare relies on data from peer-reviewed literature, not from the sponsor, and the trials generating the data must be well-designed and rigorously conducted. Additionally, CMS often requires data from multiple sources, not just one journal, which can be difficult to provide given the publishing hierarchies of the industry.

Forward-thinking sponsors must ensure their product launch plans include a solid publication strategy that outlines key messaging, identifies which journals will be targeted for publications, establishes the sequence of publications, and outlines authorship. Additionally, sponsors must incorporate the publication timeline into the product launch to account for preparing, submitting, and revising manuscripts.

2. Coding

“Codes” are used to link coverage to payment, and there are four common code sets that account for most coverage and payment resolutions:

CPT Codes
Designates procedures and services performed by health care professionals
DRG Codes
Medicare’s prospective payment system that bundles hospital payment for inpatient care
ICD-10 Codes
Used by hospitals to obtain reimbursement for services
HCPCS Codes
Indicates supplies, services, and equipment

It can take months, and sometimes years, to obtain a new code to cover a novel technology, meaning it is often more expedient to request coverage under an existing code. Sponsors that are seeking approval under FDA’s Premarket Clearance 510(k) regulatory pathway, by definition, have declared their device to be “substantially equivalent” to a predicate device currently on the market. However, relying on an established code has its own shortcomings, and the code descriptor must align with the necessary payment rates for your specific MedTech innovation. For example, if the current code pays \$500, your device will also pay out at \$500 no matter the expenses involved. This is often an unacceptable alternative if your product price point is set equal to or higher than the current code payment. As such, payments for resources and facilities will not reconcile with the revenue generated, which can slow down, or completely halt, market adoption.

When pursuing coverage from payers through an established code, it is also important to understand their stance on your predicate device. If your predicate device/procedure is currently not covered by the payer, it may be counterproductive to make any sort of comparison to a device/procedure they deem unproven. In other words, even if your predicate device is the best comparator to obtain regulatory approval, it may not be the best choice to obtain optimum payer coverage and reimbursement. So, choose wisely and with guidance.

3. Payment

The last consideration for a reimbursement strategy is “Payment.” This is the actual amount paid to the healthcare provider (clinician, clinic, hospital, etc.) for use of the device. This technically does not account for the device itself, but rather for the procedure that uses the device. However, in most cases, device payment is bundled into the overall procedure.

As mentioned previously, payment can be a critical consideration when working with a predicate device. At the same time, negotiating any payment that does not effectively reconcile with your resources and facilities can have serious consequences. These situations are completely unsustainable, and they often result from a lack of proactive planning — planning that considers coverage, coding, and payment as part of a larger strategy.



The Payoff

Early trial planning and development are paramount to a successful product launch and the generation of target revenues. By building a reimbursement strategy that effectively considers coverage, coding, and payment, every step of the reimbursement process becomes easier:

- ✓ Obtaining initial approval from CMS using peer-reviewed, published literature
- ✓ Selecting, or not selecting, an established code and predicate device for comparison
- ✓ Negotiating payments that satisfy the bottom line and encourage market adoption

How do you do it? Without the right guidance, building a robust reimbursement strategy can be a long and frustrating process. However, with the right guidance — like the guidance offered from the leading MedTech experts at Avania — developing and integrating the right strategy at the right time will ensure that the optimum predicate device is selected, a publication strategy is defined, and all critical data points are identified, collected, and analyzed to accelerate market access and provide sustainable reimbursement.

What does it take to navigate the reimbursement process with complete confidence?

It Takes Avania

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Avania is an integrated global, full-service CRO with specialized expertise in medical device, novel technology, and combination products. They advance products from feasibility all the way through post-approval in analytics, clinical trials, consulting, regulatory, reimbursement, and more.