The Reimbursement Top Ten Checklist:

Understanding How Coverage, Codes and Payment Impact the Success of a New Medical Technology

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The product design is flawless. The clinical trial endpoints were met. FDA has given the green light to begin marketing. Manufacturing has ramped up and can accommodate distribution deadlines. The plan is perfect; what could possibly go wrong?

Bottom line is this…no matter how unique or innovative a product, no matter how fine-tuned your internal processes, no matter how great the initial demand, in order to be successful in today's marketplace, everybody needs to be paid. As the spine and orthopaedic industries continue to invent and innovate, it is more critical now than ever before to ensure that these emerging technologies are appropriately ***reimbursed.***

Within the past decade, reimbursement has become a critical influencer to the success of a technology. Suddenly, navigating the maze at FDA seems elementary when compared to the reimbursement conundrum. This presents new challenges for both spine and orthopaedic device manufacturers.

Payers, both government and commercial, have become more stringent with their coverage guidelines. What was considered reasonable and necessary in the past is now under scrutiny for long term data and cost effectiveness outcomes. Medicare has been tasked by the Federal government to contain costs. As a result, our end user customers suffer. Hospitals, ambulatory surgery centers and physicians have experienced steadily declining payments.

Companies that understand these challenges, and take a *proactive* approach of integrating the reimbursement strategy into the business plan during the development phase, will be well positioned for success. ***Build it and they will come*** has become an anomaly in the spine and orthopaedics industry. Even some of the most promising technologies have failed because of lack of reimbursement.

There is often a stark contrast in the perception of what companies think they know about reimbursement and what they really understand. Not all new technologies will have favorable reimbursement at the onset. This is to be expected, so don't panic. A well-thought-out reimbursement plan, considering the needs of the key economic stakeholders, will position a technology for future success in this cost-conscious healthcare environment.

So, where do you begin? The following checklist highlights key drivers that will determine the current reimbursement landscape of a medical technology.

More importantly, this information will define the strategy and allow companies to have a well-designed strategic reimbursement plan *early*, impacting success in the future.

1. Who are the key stakeholders?
   - Specific setting of care
   - Healthcare professional
   - Insurance entity

   Who will be purchasing, using and paying for the product or procedure?

2. Are there existing codes? What are they?
   - CPT® (Current Procedural Terminology)
   - ICD-9-CM (International Classification of Diseases - 9th Revision Clinical Modification)
   - HCPCS (Healthcare Common Procedure Coding System)

   If so, have the codes been validated as appropriate for use through the appropriate entities? Codes are never determined in a boardroom. If you are not sure, seek the advice of the Professional Society, American Medical Association or CMS.

3. What is the payment?
   - Physician (Relative Value Units/RVU)
   - Hospital Outpatient Department (Ambulatory Payment Classification/APC)
   - Ambulatory Surgery Center (APC)
   - Hospital Inpatient (Diagnosis Related Group/DRG)
   - Equipment and Supplies (Durable Medical Equipment Prosthetics, Orthotics and Supplies/DMEPOS)
   - Labs and Test (Clinical Laboratory and Diagnostics Fee Schedule)

4. Who is the target patient population and what is the associated payer mix?
   - Medicare
   - Commercial insurance
   - Medicaid
   - Workers Compensation
   - Federal or State

5. Is there competition?
   - Like product on the market today
   - Existing procedure that will be replaced with the new technology

6. How is the competition paid?

7. What is the cost of the new technology and competition?
- Manufacturer's price of technology
- Cost to perform procedure inclusive of new technology
- Competitor's price for technology
- Cost to perform procedure inclusive of competitor's technology

8. Are there existing coverage decisions, either positive or negative, impacting the new technology or the competition?
- Medicare (national and local)
- Non-Medicare
  Review the coverage decisions of both payer entities. Government and commercial plans may have different coverage provisions. It is also critical to know the anticipated patient population.

9. Is there published data available for the new technology and competition?
- Peer reviewed journals
- Technology assessments
- Professional society guidelines
  Payers and the societies require well-designed clinical studies. Randomized, controlled, multi-centered U.S. studies are preferred. If there is no data available, develop the publication strategy to meet the needs of the key stakeholders as well as the company milestones.

10. Will current payment be adequate to cover the cost of the procedure with the new technology incorporated?
- Review cost analysis
- Create stakeholder financial model with anticipated payer mix
  Costs and charges are not the same. Know the cost of a procedure to your target customer. Sources are available to the public that contain procedure cost and utilization data.

Kelli Hallas is the Executive Vice President of Reimbursement at Emerson Consultants, Inc. in Minneapolis. With over twenty years of experience in the Medical Device sector, she has developed and implemented strategic initiatives for both start-up and established companies in the areas of reimbursement, sales and marketing and clinical research. In addition, Kelli has worked with the Centers for Medicare and Medicaid Services and the American Medical Association to establish new coding categories for emerging technologies. Contact the author at kellih@emersonconsultants.com.

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