

The Reimbursement “Top Ten” Checklist™

UNDERSTANDING HOW COVERAGE, CODING, AND PAYMENT IMPACT A MEDICAL TECHNOLOGY

The product design is flawless. Physicians are excited about the technology. The clinical trial endpoints will capture the necessary data for approval. The FDA discussions have occurred and the green light given to move forward. Manufacturing has ramped up to accommodate distribution deadlines. The entire plan is perfect, what could possibly go wrong?

Bottom line is this. No matter how unique or innovative a technology may be, no matter how fine-tuned the internal processes are, no matter how overwhelming the initial demand for the product is, in order for a medical technology to be successful in today’s marketplace ***everybody needs to be paid.***

As companies continue to emerge, invent, and innovate, it is absolutely critical now more than ever before, to ensure these emerging technologies are appropriately reimbursed.

“Build it and they will come” is an anomaly in today’s cost-conscious healthcare environment. Successfully launching a new medical technology is challenging, especially when it comes to securing positive reimbursement for that technology. Not only are companies under pressure to satisfy regulatory needs of the Food and Drug Administration (FDA), they also have to satisfy strict requirements from the Centers for Medicare and Medicaid Services (CMS) to ensure that their products and services are adequately reimbursed.

Hospitals must cover their operating costs and adding new technologies to procedures and services without additional payment may cut into their anticipated margins. Doctors must be appropriately compensated for performing challenging new procedures that are



improvements over today’s standard of care. Insurance Companies are implementing comparative effectiveness guidelines to minimize their risk of overpayment. Companies must cover the costs associated with a new technology in order to fund future discoveries and new ventures. Investors and shareholders expect to maximize their return on investment in a company and its technology.

The past decade has witnessed reimbursement become a critical driver in the success of a technology in today’s medical marketplace. This presents new challenges for device manufacturers. Payers 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, hospitals and physicians have experienced steadily declining payments.

Ultimately, at some point in a product’s lifecycle, whether it is pre-market or post-market, it will be impacted by reimbursement. The impact of reimbursement can be either positive or negative to both the company and the key economic stakeholders. Payer coverage decisions may have an impact on the clinical trial design and the indication for use. Current payment for a procedure may affect the anticipated list price of a technology or the forecasted sales and ROI. One thing is for certain, the economic value proposition of the technology will become an integral component of the daily sales cycle.

Companies who take a proactive approach to reimbursement with a well-designed strategy, integrated into the business plan during the development phase and align it with the clinical, regulatory, and marketing plans will be well positioned for success. The reimbursement strategic plan should be forethought, not an afterthought. Waiting until commercialization to focus on the reimbursement plan will be too late.

There is often a stark contrast in the perception of *what investors want to know* and *what companies understand* pertaining to the reimbursement of a new technology. Not all breakthrough and emerging technologies will have favorable reimbursement at the onset. This is to be expected, so don’t panic. Payers require outcomes data from well-designed clinical trials to establish coverage and payment. CMS requires procedure cost data to determine an appropriate payment rate. Professional societies want to see technology adoption from their members and peer reviewed journal articles to support procedure codes and payment. Unfortunately, none of this happens immediately.

As due diligence progresses on a new technology, it is important not to fixate on what the landscape is or is not today. Instead, companies must focus on developing a solid reimbursement plan for favorable future positioning. Reimbursement is a dynamic entity. Coverage, codes, payment, and competition are constantly changing. A well-designed strategy, addressing the critical drivers impacting the reimbursement for a new technology is as critical as the clinical trial protocol or the regulatory strategy.

So, where do you begin the reimbursement due diligence for a new medical technology? What are the critical factors to identify and incorporate into the strategy? What are the main elements that are imperative to know?

The Reimbursement Top Ten Checklist highlights those key drivers of reimbursement that will impact the success of a new technology and provide companies and investors with the critical information necessary to determine the current reimbursement landscape. More importantly, this information will define the reimbursement strategy and allow companies to have a well-designed strategic reimbursement plan **early**. Remember, the longer the wait, it may be too late!

Kelli Hallas, Executive Vice President of Reimbursement
Emerson Consultants, Inc.

1. Who are the key stakeholders?

- Specific settings of care
- Healthcare professionals
- Insurance entities

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 to report the new technology 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 (Medicare).

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 US 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. It is imperative to know the cost of a procedure to your target customer. Sources are available to the public that contain procedure cost and utilization data. If adding technology to an existing procedure, incorporate the cost of the technology into the procedure’s current cost. If replacing a component of a procedure, or providing other cost savings (reduced procedure time, reduction in follow up treatment, shorter ALOS) incorporate those reductions into the procedure cost.

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 and Biologics sectors, 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.

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