Understanding how Coverage, Coding, and Payment Impacts a New Medical Technology

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Early Strategy Integration is CRITICAL to any Product’s Success
Why is Reimbursement Important?

- Ultimately, at some point in a product’s life cycle, it will be impacted by reimbursement.
- Rising healthcare costs (direct and indirect) are cutting into hospital and physician profit centers and they are responding.
- A well-designed reimbursement strategy, integrated early in the development phase with regulatory, clinical, and marketing strategies can impact the pendulum to swing to the positive.
- Bottom line…if there is no reimbursement, it will not sell.
“Build it and they will come” is an anomaly in today’s cost conscious healthcare environment

Everyone needs to be paid

Some of the most promising technologies have failed because of lack of reimbursement due to no early planning
Payers have become more stringent with coverage guidelines.

“Comparative Effectiveness”, “Substantial Clinical Improvement”, and “Medical Necessity” are the new buzz words.

Medicare is running out of money and is tasked to contain costs.

Washington is trying to figure out the future of healthcare.

Physicians and hospitals are experiencing steadily declining payments.

Med Tech companies and investors are not experiencing the same return on investments that they had become accustomed.
Is Healthcare Reform Good or Bad?
Depends on Who You Ask!
Expanded Market Share

- 32 million potential new customers
- Removal of lifetime caps
- Coverage for pre-existing conditions
- Expanded coverage for preventive services
Reform Initiatives

- Device and Pharma companies “Pay to Play”
  - Excise tax of 2.3% applicable to all device manufacturers regardless of size
- Pharma required to give significant discounts on brand names to Part D plans
- Increase Focus on Performance Measurements
  - Moving from “Carrot” to the “Stick” Approach
- Changes in payment methodologies
  - Moving away from fee-for-service (i.e. Accountable Care Organizations)
What can we do?

What can companies do TODAY, even if only in the development phase to ensure a positive pathway to reimbursement and support fundraising efforts and the needs of investors?
Start Early, Start Early, Start Early

When you are at the starting line you need to see the finish line!
Reimbursement Can Be Confusing!
Product Design
- R&D must understand the need to show clinical value
- Diagnostic vs. therapeutic

Setting of Care
- Different reimbursement based on site of care

Provider type
- Surgical vs. Medical; Physician vs. Non-physician

Clinical Indications
- Define subset of patients. Include target patients in clinical trials
Understand how the Elements of Reimbursement Apply to Your Product

- Coding
  - Are there existing codes or is a new code(s) required? If new codes are needed, how long will it take and what can be used until it is available?

- Coverage
  - Is coverage in place? What is your coverage strategy? What kind of data will be required?

- Payment
  - Is payment adequate to support your pricing? If not, what steps should be followed and how long will it take?

“Staying under the radar” is not a strategy
Coding…The Big Ticket Question

- Used to report procedures for payment
- The type of code reported for a service or procedure varies by setting of care and the healthcare provider
- All codes are researched in the assessment and addressed (if necessary) in the strategy
- Words of wisdom………………
Codes are NOT Determined in a Boardroom

- Validate all codes with the gatekeepers
  - Societies
  - AMA
  - Consultants
  - Payers
  - Medicare

- Sometimes the best intentions will get you into trouble
Process to Get New Codes

- **New CPT code (procedure payment)**
  - AMA controls CPT process
  - Takes an average of 18-24 months after FDA approval
  - Political process, must have physician specialty support

- **HCPCS code (device/supply)**
  - CMS controls HCPCS codes; applications accepted on calendar year schedule

- Can be 18-24 month lag since process starts after FDA approval
The decision to pay, or not to pay, for an item or service on behalf of a beneficiary:
- Is it medically reasonable and necessary?
- Will it diagnose or treat a patient’s medical condition?
- Does it impact net health outcomes?
- Does it meet the standards of good medical practice?

May be favorable, unfavorable, or limited in nature.

In the end, coverage is driven by…
DATA!

Scientifically sound clinical evidence

*Every study is a “reimbursement” study!*
Payer Coverage is Based on Evidence

- Work with the clinical team early on to identify endpoints and study design that are meaningful to payers and demonstrate the product value.

- If Medicare patients are part of the target patient population, always include Medicare patients in the trial.

- Even if Medicare is not the primary payer, it is still important:
  - Largest payer in the U.S. (and growing)
  - Considered bellwether
  - Other payers often follow Medicare’s lead on coverage
  - Non-coverage decision by CMS can create a ripple effect with private payer policies.
Clinical evidence will become even more important!

- Increased expectation on level of evidence
- CER will compare competitive products (not just placebo or standard treatment)
- Clinical evidence is not only needed for coverage, but payment (“clinical improvement” is required)

Remember that you can get payment for your clinical trial
Clinical Trial Considerations

- Many clinical trials are eligible for reimbursement (Category B IDE status)
- If done correctly, does not have to delay enrollment
  - Can secure Medicare approval prior to starting trial
- May reduce expense of doing clinical trial
- Collects claims data and cost effectiveness that will be required by payers
Must have a Coverage Strategy

- No longer writing blanket coverage decisions
  - Requires data!
- Payers are looking at the subset of patients who have best outcomes
  - (i.e. Only Type 1 patients with diabetes or patients who have failed standard therapies)
- Consolidated decision making within Medicare
  - NCD vs. LCD, MACs result in fewer decision makers
Criteria Impacting Coverage

- FDA approval/clearance (if not in clinical trial or HDE)
- The technology must improve net health outcomes and the data must validate this
- Must be better than or equal to the current standard of care
- Improvement must be attainable outside of the investigational setting
- Peer reviewed, US journal data must be available citing compelling outcomes data
Is the current payment rate adequate to cover the cost of the procedure and/or the device to both facility and doctor?

Collect economic data (hospital bills) to validate procedural costs to substantiate need for additional payment

- Re-assign DRG placement
- Re-assign APC placement
- Obtain add-on payment in the inpatient setting
- Obtain pass-through status in the outpatient setting

You will still need good clinical data to substantiate the value of the product.
Reimbursement and Regulatory Must be Aligned

- 510(k) clearance may appear to be the quickest and most affordable way to enter market
- Substantially equivalent = substantially equivalent payment
  - May make it more difficult to get unique coding or coverage
- 510(k) submission may not provide the clinical outcome data required by payers
Why is Integration Important?

- Can not afford to do an FDA study and a CMS/payer study
- Need to gather as much published data as possible; all with the same goal in mind
- Payers no longer cover off-label use
- Professional societies will not support/endorse a technology without sufficient data
How do you do it?

Bring the team (clinical, regulatory, reimbursement, marketing, R&D) together and review the claims matrix

Example: Marketing wants to be able to claim the technology is “faster and less expensive” what type of study will be needed to convince the FDA?
One more thing to consider..

Political strategy

- Need to watch Capitol Hill
- FDA and CMS are changing
- Need to pressure legislators
- Physicians, hospitals and Professional Societies need to help
Incorporating the Economic Value Proposition into the Sales Cycle

- Determine the economic impact the procedure will have
  - To hospital
  - To physician
  - To patient
  - To payer

- Economic value may differ by customer (payer, hospital, MD)

- Incorporate the economic and clinical value propositions into marketing materials
Must be able to Demonstrate “Value”

- Metrics are changing
  - No longer just “increase revenue or decrease costs”
  - Help achieve performance measures or avoid penalties (HACs or Never Occurring Events)
Most Important…

- Start early! Start Early! Start Early!
- Begin in the product development phase
- Integrate your reimbursement, regulatory, clinical, and marketing strategies
Case Example #1

- New technology for ischemic stroke
- Sales and Marketing responsible for Reimbursement
- Plan was to use existing codes, but not verified
  - AMA/Specialty society did not agree with existing codes
- Applied and received new ICD-9 procedure code for inpatient procedure
  - Received code before three year freeze
- Collected reimbursement data during clinical study
  - Had data to take to CMS for DRG placement
- Able to achieve coding and payment prior to FDA approval
Case Example #2

- Received call after FDA approval
  - Tactical rather than strategic
- Convinced “product was different” than existing technologies
  - Non-coverage policies for existing technologies
  - Planned to use existing CPT codes
- Spent first 18 months of launch fighting coverage, coding and payment
Case Example #3

- Started reimbursement strategy early during product development
- Market data was focused on Type II diabetes
  - Insulin pump coverage exists for Type I
  - Started clinical studies for Type II
- Medicare changed definition of DME to require 3 year life expectancy
  - Changed product design
- Had time to develop reimbursement strategy
In Summary... Does Reimbursement Really Matter?

- YES!
- Ultimately at some point in a product’s life cycle it will be impacted by reimbursement
- The impact can be negative or positive
- A well-designed reimbursement strategy EARLY in the development phase will have a positive impact on the product or procedure AND maximize the value of your company
- Bottom line...if there is no reimbursement, it will not sell. If there is reimbursement, or a solid strategy to secure it, they will buy it
QUESTIONS?

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