The Fundamentals of Reimbursement

Understanding How Coverage, Coding, and Payment Impact a Medical Technology

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Brand manufacturers should contact the appropriate entities for product-specific coding guidance. The examples cited in this presentation are based on literature searches, educational programs, and a review of hospital claims. Final coding is at the discretion of the healthcare provider.
Objectives

- Develop a basic understanding of the key drivers of reimbursement
- Identify the critical elements to incorporate into a solid reimbursement strategy to have a positive impact on a new technology
- Understand the importance of well-designed clinical studies and data to medical technology reimbursement
- Create a working checklist of the key reimbursement elements to understand pertinent to a medical technology
Why Develop a New Medical Technology?

1. Physician had a great idea (presented on a napkin)
2. Engineers can build it
3. Marketing says they can package, brand, and create the need
4. Sales says they need it and can sell it
5. Board expects it
6. Shareholders demand it
7. Competition does not have it
8. Patients want it (internet blogs told them so)
9. Regulatory says it is a 510(K) not PMA
10. Clinical says no study necessary, just sell it
Better Reasons

- The technology will provide substantial clinical improvement over the current standard of care
- It will provide an economic advantage
- Medicare will pay for it
- Payers will cover it
- Hospitals can afford it
- Physicians will want it to benefit their patients
- Patients will demand it
But Given All That
The Question Remains…

Will it be Reimbursed?
By whom? How much? What’s the ROI?
The Playing Field has Changed

“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
The Paradigm Shift

challenges of the past decade

- Payers have become more stringent with coverage guidelines
- “Comparative Effectiveness” 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 to
What can companies do TODAY, even if only in the development phase to ensure a pathway for positive reimbursement tomorrow?
Start Early, Start Early, Start Early

When you are at the starting line you need to see the finish line!
There is often a stark contrast in the perception of what companies need to know and what companies think they understand pertaining to the reimbursement of a new technology. The more you understand about the reimbursement landscape impacting a technology the more bullet-proof the strategy. There is no such thing as “too much” reimbursement intelligence.
Reimbursement Can Be Confusing!
Understand What Reimbursement Is

Reimbursement is the actual *payment* received by the healthcare provider (physician or facility) for services provided to a patient.

Or in other words…………………..
Show Me the Money!!!
Three key drivers of reimbursement: coverage, codes, and payment

Although considered a “single” entity, Reimbursement is the interaction of these separate, yet distinct aspects of the healthcare system.
Coverage…It all begins here

- The decision of the insurance company 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…

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DATA!

Scientifically sound clinical evidence
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
Key Takeaway Relative to Coverage…
Regardless how unique the product design….

No evidence
Scientifically sound clinical data

No coverage
Not proven medically necessary

No payment!

No sales=
No revenue!
Key Coverage Activities

- If special requirements for coverage are listed in the medical policies, include them in the protocol if performing research or include them in the IFU
  - BMI
  - age
  - prior failed therapies
  - number of treatments

- Meet with CMS (Medicare) to discuss the procedure
  - FDA and CMS have different needs
    - reasonable and necessary vs. safety and efficacy

- Meet with individual payers to educate them and get their perspective on the technology
Key Coverage Activities (cont.)

- Align with key opinion leaders who have experience with the technology to advocate for coverage
- Meet with Professional Societies to incorporate technology into practice guidelines (payers will contact the Society)
- Validate the publication strategy will meet coverage timelines
Coding…The Big Ticket Question

- Used to report procedures for payment
- The type of code reported will vary by setting of care/healthcare provider
- Contrary to popular belief codes are never determined in a boardroom
  - validate with appropriate gatekeepers
  - the best intentions can get you into trouble!
Types of Codes

ICD-9 Diagnosis

*International Classification of Diseases 9th Revision Clinical Modifications*
- signs, symptoms, or conditions
- the “why” a patient is receiving treatment
- have no direct payment value but influence hospital payment

- 722.52 degeneration of lumbar or lumbosacral intervertebral disc
- 724.02 spinal stenosis lumbar region w/o neurogenic claudication

All healthcare providers report ICD-9 diagnosis codes whenever a claim is submitted

Why important?
- Labeling and product claims
- Payer coverage decisions
Types of Codes

ICD-9 *Procedure*
- reported by hospitals to report *inpatient* procedures
- the “what” is being performed
- can be assigned during an IDE trial-no need for FDA approval
- have no direct payment value

- 84.80 insertion or replacement of interspinous process device(s)
- 84.62 insertion of total spinal disc prosthesis, cervical

Controlled by CMS (Medicare)

Why important?
- procedure tracking for clinical outcomes and economic data
- payer coverage decisions
Types of Codes

**CPT®-4 Codes**


- used by physicians, hospital outpatient departments, ASC’s, freestanding facilities
- describe surgical, non-surgical, and diagnostic procedures
- have a direct payment value unique to the healthcare provider
- Category I (permanent code, has RVUs established to determine payment)
- Category III (temporary code, no RVUs, payment varies, used for procedure tracking)

- 22524 Percutaneous vertebral augmentation, including cavity creation using mechanical device, one vertebral body, unilateral or bilateral cannulation (kyphoplasty) lumbar
- 0171T Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance) lumbar, single level

*Controlled by the AMA*
Types of Codes

**CPT®-4 Codes**

**Why important?**
- differentiates procedures by specific approach
- has direct payment value to each stakeholder

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Category I
CPT® Code Requirements

- FDA approval for specific use
- It is a distinct service (not fragmented)
- Efficacy is well documented in US peer-reviewed literature (5 articles-different studies preferable) - again data is critical
- Widespread use outside of investigational setting
- Societal support
Category III
CPT® Code Requirements

- Clinical trial protocol established
- Support from the specialty society
- Availability of some US peer reviewed literature
- Descriptions of current US trials outlining the efficacy of the procedure
- Category III codes are becoming more widely accepted
HCPCS codes are reported by hospital outpatient departments and ASC’s to identify services, supplies, and products not included in the CPT code for the procedure.

- Identify DME, supplies, drugs, non-physician services, orthodics/prosthetics
  - C1821 interspinous process distraction device (implantable)
  - C1776 joint device (implantable)

Some HCPCS codes have a fee schedule payment rate associated with them.

Some HCPCS codes are linked to payment by special payment arrangements.
And Finally…Payment!

Physician Payment

Facility Payment
Payment

- Payment is dependant on coverage and coding
  - if there is a positive coverage decision and there is an existing code, payment will be made
  - if there is a positive coverage decision and no specific code (unlisted or Category III), payment will be made
  - if there is a negative coverage decision and there is an existing code, no payment will be made
  - coverage is CRITICAL!

- The type of code reported will determine which payment methodology is used

- Healthcare Providers (physicians and facilities) are paid according to different methodologies, and most often, separate from one another
Physician Payment

- CPT® codes drive physician payment

- Medicare will reimburse physicians according to the Medicare Physician’s Fee Schedule (MPFS) which is based on RVUs (relative value units)

- Commercial plans reimburse physicians according to a variety of methodologies

- Final determination is per the terms of their negotiated contract for payment

- Medicare is a benchmark for payment
Hospital Outpatient Payment

- Hospital Outpatient Procedures are paid based on the value of each CPT code reported to describe the entire procedure.
- Medicare reimburses hospitals according to the APC (Ambulatory Payment Classification) the CPT code is assigned to.
- Commercial plans reimburse hospitals according to a variety of methodologies.
- Final determination is per the terms of their negotiated contract for payment.
- Medicare is a benchmark for payment.
Hospital Inpatient Payment

Inpatient procedures (ICD-9 procedure codes) are assigned to a DRG (Diagnostic Related Group) by Medicare.

The combination of the reported ICD-9 procedure code AND the ICD-9 diagnosis code determine the final DRG placement (and payment from Medicare).

Commercial plans reimburse hospitals according to a variety of methodologies.

Final determination is per the terms of their negotiated contract for payment.

Medicare is a benchmark for payment.
ASC Payment

- Report procedures by the use of CPT® codes (same as surgeon and hospital outpatient)

- Medicare designates only certain procedures allowable for reimbursement in the ASC (Medicare beneficiaries)

- Commercial plans have authority to pay for non-Medicare approved procedures

- Medicare pays ASCs according to the APC methodology at a discounted rate of the hospital outpatient payment for the eligible procedures~67% of the Medicare OPPS rate

- Commercial payers will reimburse based on the terms of their individual contracts
Key Takeaways

- Reimbursement is impacted by coverage, codes, and payment
- There are different coding methodologies associated with the various stakeholders
- Payment will vary based on the setting of care and the individual payer
- Data is critical to reimbursement
- Partner with payers as early as you possibly can
- Find out as much information as you can, as early as you can relative to the critical elements of reimbursement impacting your product or procedure
Most Important...

- Start early! Start Early! Start Early!
- Begin in the product development phase
- Integrate your reimbursement, regulatory, clinical, and marketing strategies
What’s Important?

Now that you understand the basics, what are the critical elements to understand?
The Reimbursement
Top Ten Checklist

1. Are there existing codes for each stakeholder?
   • CPT (physician, hospital outpatient, ASC)
   • ICD-9 (hospital inpatient)
   • HCPCS (hospital outpatient, ASC)

   • What are they?
   • Have they been validated?
The Reimbursement
Top Ten Checklist

2. What is the current payment for the stakeholders (based on the codes)
   • Physician
   • Hospital Outpatient
   • ASC
   • Hospital inpatient
   • Free standing facility
   • Lab and diagnostics

Is there an opportunity to influence the payment?
3. Who is the target patient population and what is the payer mix?

- Medicare (>65 years, disabled)
- Commercial Insurance
- Worker’s compensation
- Other government (military, Medicaid)

*Coverage policies will vary by payer
*Payment will vary by payer
The Reimbursement
*Top Ten Checklist*

4. Is there competition?
   - Like product on the market today or in trials?
   - Near future?
   - Existing procedure being replaced
The Reimbursement

Top Ten Checklist

5. How is each stakeholder paid for the competitive product/procedure?
6. Are there existing coverage decisions for the new technology or the competition?

- Medicare
- Commercial
- Medicaid
- Worker’s compensation

Are they positive or negative?
Are they coming up for review?
7. Is published data available for the new technology and/or the competition?
   - Peer reviewed journals
   - Technology assessments (BCBS Tec, ECRI, HAYES)
   - Professional society guidelines

Remember…..
DATA IS CRITICAL TO REVENUE

No evidence
Scientifically sound clinical data

No coverage
Not proven medically necessary

No Payment!

No revenue!

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8. What is the cost of the new technology and the competition?

- Manufacturers price
- Cost to perform procedure inclusive of new technology
- Competitors price
- Cost to perform procedure inclusive of competitors technology
- Determine all stakeholder’s ROI
- Determine net health outcomes
9. Will current payment be adequate to cover the cost of the procedure with the new technology incorporated?

- Review cost analysis
- Hospital financial analysis with payer mix incorporated

Remember...cost and charges are not the same!
10. Is there a well-defined reimbursement strategy? Has it been integrated into the clinical, regulatory, sales and marketing plans early?
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.
- 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.
Reimbursement is a constant challenge for all stakeholders in today’s cost-conscious healthcare environment.

Empowering yourself with knowledge relative to the fundamentals of reimbursement will enable you to design and implement a comprehensive reimbursement strategy that will prove valuable to your company, your customers, and your stakeholders. Ultimately, making a positive impact on your company’s bottom line.
Words of Wisdom…

Positive reimbursement for a product or procedure rarely is instant
The important question is “what’s the strategy?”
Thank You

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