

# The Reimbursement Strategy

## How to Successfully Impact Your Economic Value Proposition

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# Why Does Reimbursement Matter?

- 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, integrated 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. If there is reimbursement they will buy it.



***It Pays to Integrate***



# The Reimbursement Value Proposition

- 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. KH2003



# What is Reimbursement?

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

Or in other words.....

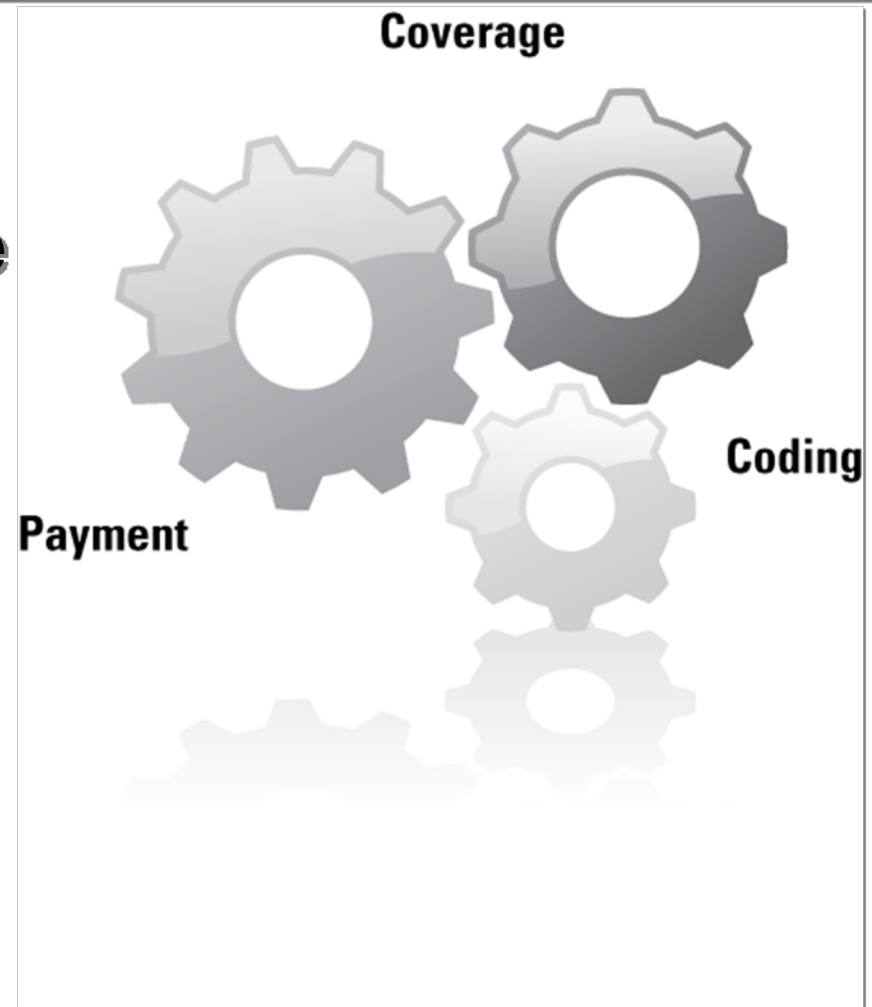


# Show Me the Money!!!



# Key Drivers of Reimbursement

- Although considered a “single” entity, **Reimbursement** is the interaction of these separate, yet distinct aspects of the healthcare system.
- All three need to be incorporated into the reimbursement strategy.



# The Reimbursement Assessment

## *the pre-work*

- Performed early in the conceptualization phase.
- Determines current “reimbursement landscape” for a product/procedure
  - ▶ Coverage
  - ▶ Coding
  - ▶ Payment
- Determine competitive landscape.
- The assessment will help define your strategy.



# Coverage...It all begins here

- **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**

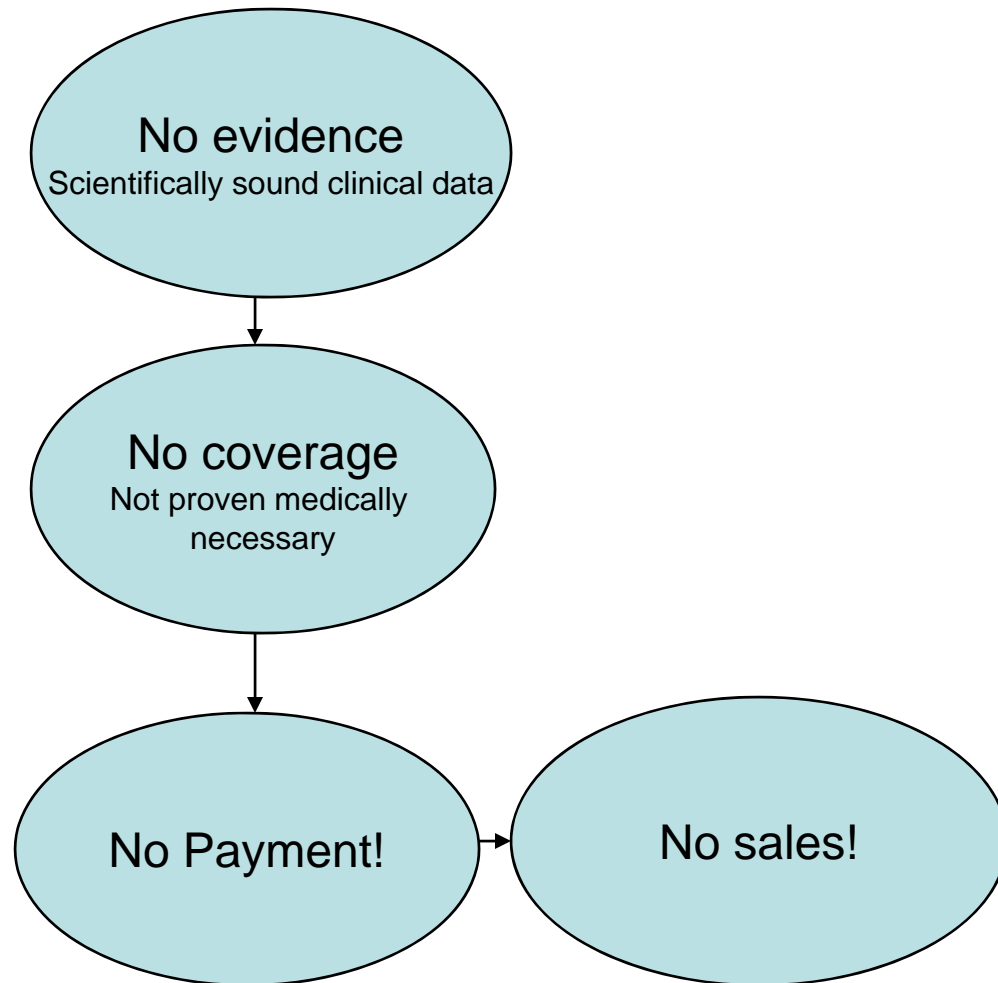


# Criteria Impacting Coverage

- FDA approval/clearance.
- The technology must improve the net health outcomes, and your 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.



# Key Takeaway Relative to Coverage...



# How Coverage Decisions Impact Revenue

- Morbid obesity surgery
- Lumbar artificial disc replacement



# Negative Decision = Negative Revenue

- Example of a negative coverage decision that had a negative impact on company revenue.
- Lumbar artificial disc replacement



# The Coverage Strategy

- Coverage decisions for procedure and/or disease are reviewed in the initial reimbursement assessment.
- If special requirements for coverage are listed in the medical policies, include them in the protocol.
  - ▶ BMI
  - ▶ Age
  - ▶ prior failed therapies
- Meet with Medicare early. FDA and CMS have different needs. Incorporate CMS needs into the protocol.
- Meet with individual payers (post approval) to secure positive coverage and influence requirements and guidelines (need data).



# The Coverage Strategy (cont.)

- **Align with key opinion leaders who have experience with your technology to advocate to the payers for coverage.**
- **Meet with Professional Societies to incorporate technology into practice guidelines (payers will contact the Society).**
- **Validate 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.
- **All codes by setting of care need to be addressed in the strategy.**



# Types of Codes

## ● ICD-9 *Diagnosis*

*International Classification of Diseases 9<sup>th</sup> Revision Clinical Modifications*

- ▶ signs, symptoms, or conditions
- ▶ the “why” a patient is receiving treatment

## ● 278.02 morbid obesity

## ● V84.7 BMI >40

● Defined within your clinical protocol.

● Parallels your regulatory pathway.

● Directly impacts your labeling and claims.

● Payers will cover “on label” indications.



# Types of Codes

## ● ICD-9 *Procedure*

- ▶ reported by hospitals to report **inpatient** procedures
- ▶ can be assigned during an IDE trial-no need for FDA approval

● 37.27 cardiac mapping

● 84.62 insertion of total spinal disc, cervical

● Defined within your clinical protocol.

● Will allow collection of procedural-specific economic data (cost) to possibly impact payment.



# Types of Codes

## ● **CPT®-4 Codes**

### *Current Procedural Terminology 4<sup>th</sup> Edition*

- ▶ Used by physicians, hospital outpatient departments, and ASC's.
- ▶ Describe surgical, non-surgical, and diagnostic procedures.
- ▶ Have a direct payment value unique to the healthcare provider (physician payment different from ASC or HOPD).
- ▶ Controlled by the AMA.

● **22524** Percutaneous vertebral augmentation, including cavity creation using mechanical device, one vertebral body, unilateral or bilateral cannulation (kyphoplasty) lumbar

● **52647** laser coagulation of the prostate



# The Coding Strategy

- Coding research for all settings of care is performed during the initial reimbursement assessment.
- Determine if codes already exist or if new codes need to be created.
  - ▶ Determine correct coding relative to ICD-9 and HCPCS with CMS
  - ▶ Determine correct coding relative to CPT with Professional Society and/or AMA
- If a new CPT code is needed ensure your coding strategy is aligned to satisfy special criteria
  - ❖ 5 peer reviewed US journal articles
  - ❖ FDA approval
  - ❖ Widespread use
  - ❖ Society support

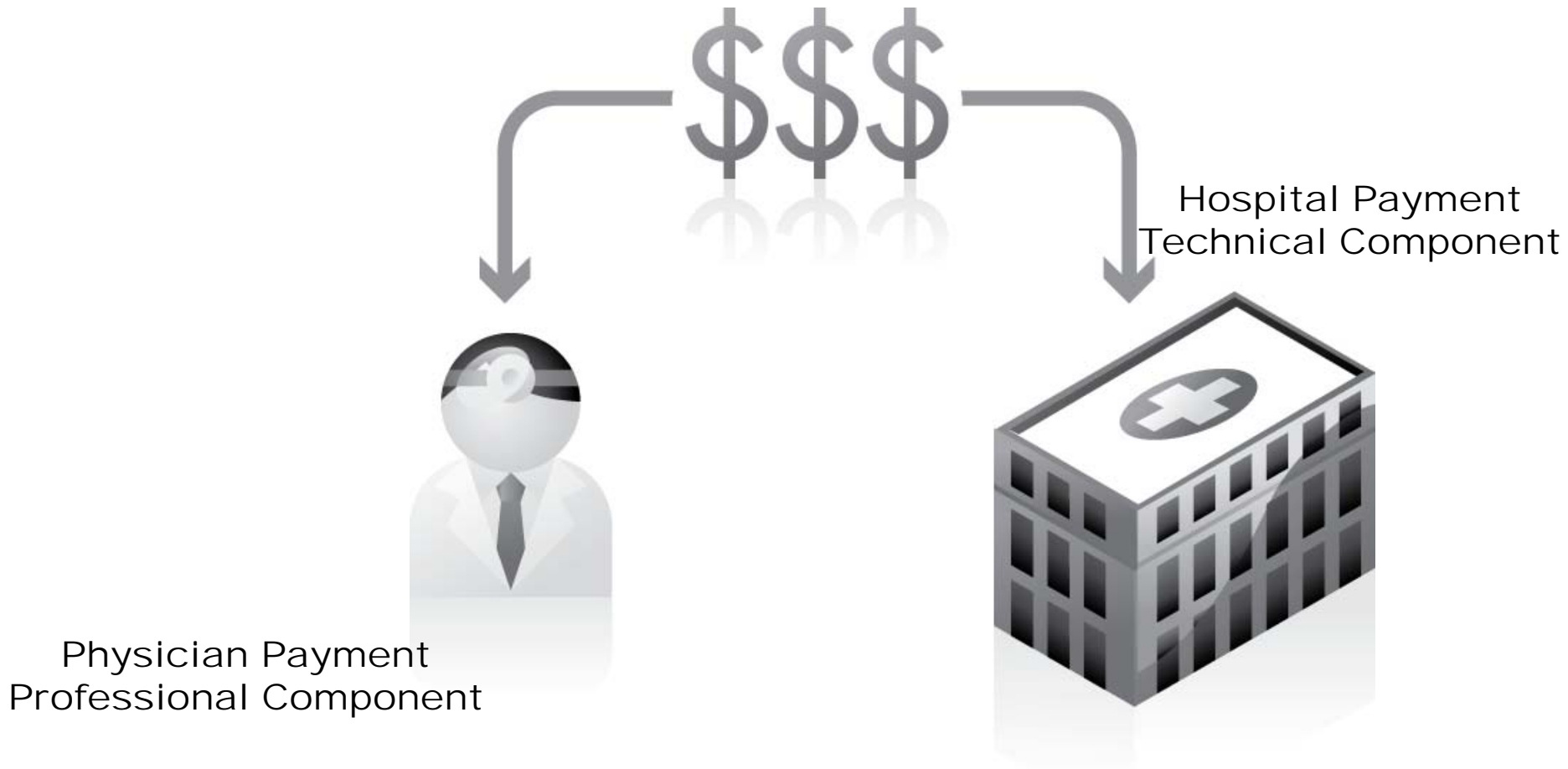


# The Coding Strategy (cont.)

- Meet with Professional Society CPT chairperson.
- Meet with chair to discuss procedure, current coding options, and proposed coding strategy.
- Determine if Society has additional needs.
- Align with KOLs who support your technology to advocate for your procedure and the need for a code to the Society and/or the AMA or CMS.
- ICD-9 procedure
  - ▶ No codes presently exist to accurately classify procedure
  - ▶ May be in IDE clinical trial
  - ▶ Instead of creating a new code, CMS may revise nomenclature of an exiting code
- Your data is critical-review your publication strategy! Is it on track?



# And Finally...Payment!



Physician Payment  
Professional Component

Hospital Payment  
Technical Component



# Payment

- Payment is dependant on coverage and coding.
  - ▶ If there is a positive coverage decision and there is an existing code, then payment will be made.
  - ▶ If there is a negative coverage decision and there is an existing code, no payment will be made.
- Healthcare Providers (physicians and facilities) are paid according to **different methodologies**, and most often, separate from one another.
- Payment for each provider is identified in the assessment.
- Payment for each provider is identified in the strategy.



# Physician Payment

- Payment rates for physician procedures are identified in the reimbursement assessment.
- Medicare will reimburse physician's according to the Medicare Physician's Fee Schedule (MPFS) based on the value of the reported CPT code (RVUs).
- 22524 \$554.70
- 52647 \$665.43
- Commercial plans will reimburse physician's according to a variety of methodologies. Final determination is per the terms of their contract for payment. It's all negotiated.



# Physician Payment

- If unlisted codes are to be reported while waiting for CPT code, assist customers with obtaining payment.
  - ▶ Reimbursement tools
  - ▶ Cost analysis
- Remember, payment will be made for procedures with positive coverage even without a specific CPT code.



# Hospital Outpatient Payment

- Payment rates for outpatient procedures are identified in the reimbursement assessment.
- Procedures (CPT codes) are assigned to an Ambulatory Payment Classification (APC) which determines the Medicare payment rate.
  - 22524 \$5720.43
  - 52647 \$3026.08
- Use Medicare rates as a benchmark.
- Will procedural costs be covered?



# Hospital Inpatient Payment

- Payment rates for inpatient procedures are identified in the reimbursement assessment.
- Medicare assigns procedures to a DRG based on the combined reporting of the ICD-9 procedure code and the ICD-9 diagnosis code.
- MS-DRG 490-Back and neck procedures except spinal fusion with CC/MCC or disc device or neurostimulator
  - ▶ \$9544.56
- MS-DRG 251-Percutaneous cardiovascular procedure w/o coronary artery stent or AMI w/o MCC
  - ▶ \$8898.71



# The Payment Strategy

- Is the current payment rate adequate to cover the cost of the procedure and/or the device?
- Integrate “payment” into your pricing strategy.
- 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



# The Payment Strategy (cont.)

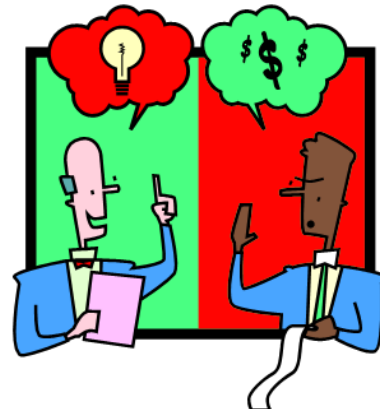
- Collect hospital data retrospectively from procedures to do cost analysis.
- Primary endpoints or secondary endpoints powered to show “substantial clinical improvement” over the standard of care
  - ▶ Reduced LOS
  - ▶ Reduced blood loss
  - ▶ Return to ADL
  - ▶ Less pain post-operative
  - ▶ Faster recovery
  - ▶ Reduction in pain meds (narcotics)
- All are required by CMS to obtain additional payment-include in clinical trial strategy/protocol.



# The Sales Strategy: 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



- Integrate with Marketing to create the message.
- Incorporate the economic and clinical value propositions into marketing materials.



# Support Your Sellers

- Create training programs and support materials for your sellers.
  - ▶ Healthcare providers rely on industry to keep them informed
  - ▶ Sellers need to understand the current reimbursement landscape of the product/procedure
  - ▶ Uninformed sellers may provide incorrect information
- Providing economic information early will reduce the length of the sales cycle.



# Thank You

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