How to Explain Device Reimbursement to your CEO

The Medical Device Regulatory and Compliance Congress

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March 29, 2006

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A few questions you don’t want to hear from your CEO…

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A few questions you don't want to hear from your CEO…

How can CMS deny coverage for our new technology?

FDA has approved it.

Should I call Mark McClellan or our member of Congress?

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A few questions you don't want to hear from your CEO…

It is too expensive and time consuming to do a clinical trial.

We need to find a way to get CMS to cover this technology based on existing evidence.

We can do this, can't we?

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A few questions you don't want to hear from your CEO…

I just spoke with Jack, the CEO of our competitor, Advanced Systems, and he said they got a new CPT code for the neuro device.

How come we didn't take the lead on this?

What should I tell our customers?

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A few questions you don't want to hear from your CEO…

Can't we just let AdvaMed and the big companies carry the weight on reimbursement policy issues?

We are too small and can't afford to get engaged.

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A few questions you don't want to hear from your CEO…

It will be hard to increase headcount this year.

Do we really need 2 full-time reimbursement staff?

Can't we prioritize reimbursement projects?

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Now, the questions you do want to hear and how to answer them

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Questions you do want to hear

I've been hearing a lot recently about reimbursement. How important is it to our company?

Could you provide me with a 101 on how reimbursement works? We have around 15 minutes.

What do we need to do to be successful in obtaining reimbursement for our new products?

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Importance of Reimbursement

Regulatory approval is insufficient to get a product to market

- Obtaining reimbursement is a crucial next step

Availability of reimbursement has a direct impact on therapy adoption, can “make or break” a product

- If a new product is not reimbursed, market will be very restricted at best
- If providers are not paid adequately, they will be reluctant to provide a new therapy
- Reimbursement affects market size, not market share

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Importance of Reimbursement

Inadequate reimbursement can negatively affect the stock price and availability of venture capital

Provide examples of new products in your therapy sector that failed due to lack of reimbursement

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How Reimbursement Works

Each country has its own reimbursement system

The US healthcare system involves multiple government and private payers

- Reimbursement processes differ by payer type

Regulatory approval and reimbursement are separate processes

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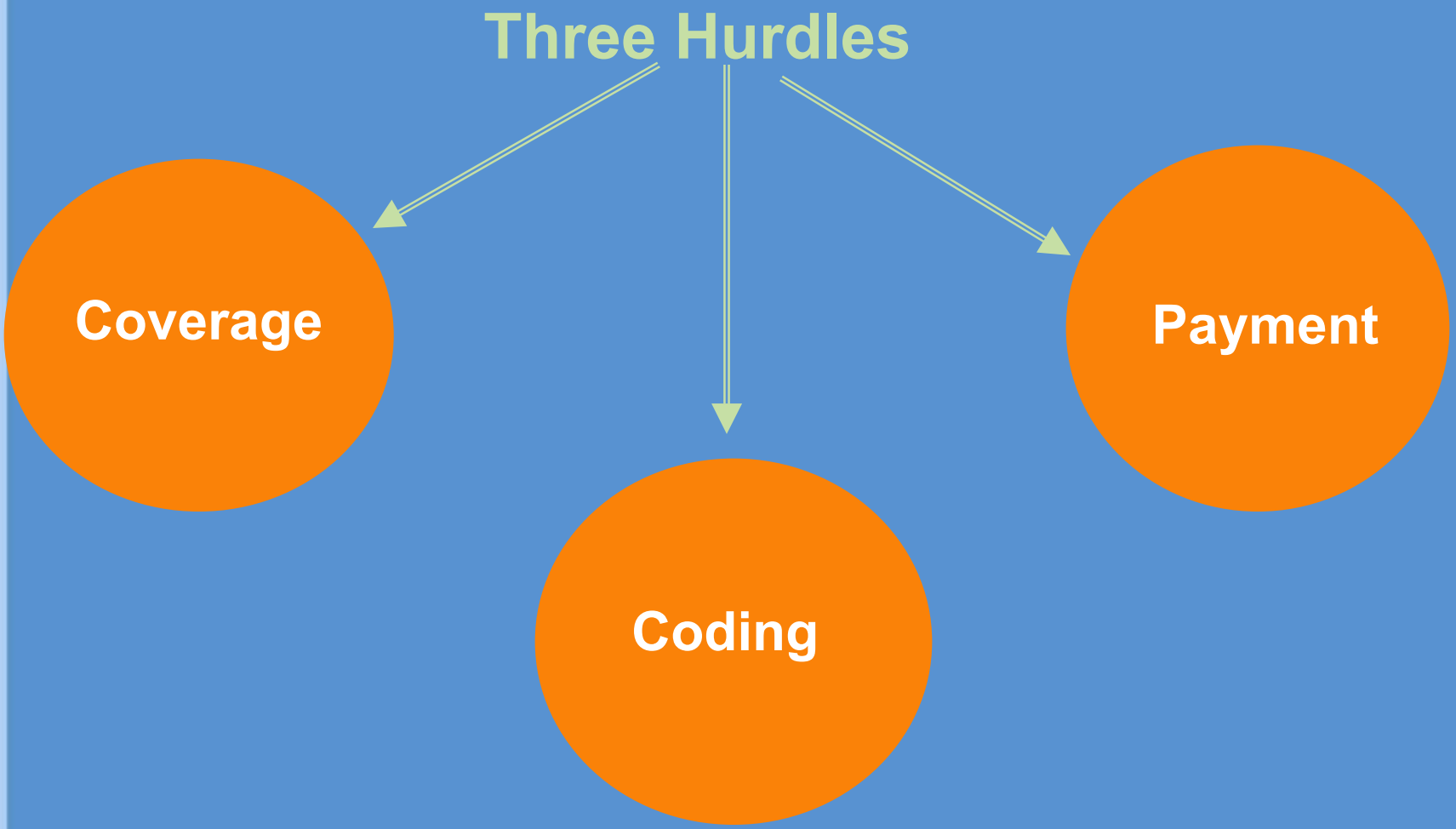
Reimbursement for New Technologies



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Coverage, Coding and Payment

Step 1

Is procedure covered as a benefit?

Step 2

How much will it be paid?

YES

NO

No Payment

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How Reimbursement Works

Solid clinical evidence is required to obtain coverage

- Demonstrating economic value increasingly important

Codes serve to identify new procedures/products, do not guarantee a higher payment

Need to demonstrate significant cost increase and clinical/economic value to obtain higher payment

Obtaining reimbursement takes a long time, will most likely not be available at launch

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Developing a Successful Reimbursement Program

Broad goals and strategies

External advocacy

Internal processes and programs

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Reimbursement Program Goal

Assure adequate reimbursement for new and existing technologies in order to drive therapy adoption

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Reimbursement Strategy

Shape government reimbursement policy

Pursue adequate reimbursement for specific new technologies

Provide customer support

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External and Internal Strategies

External Advocacy

- ✓ Build relationships
- ✓ Pursue advocacy initiatives
- ✓ Obtain stakeholder support

Internal Capabilities

- ✓ Educate key staff
- ✓ Establish processes
- ✓ Integrate reimbursement into product life cycle
- ✓ Develop evidence

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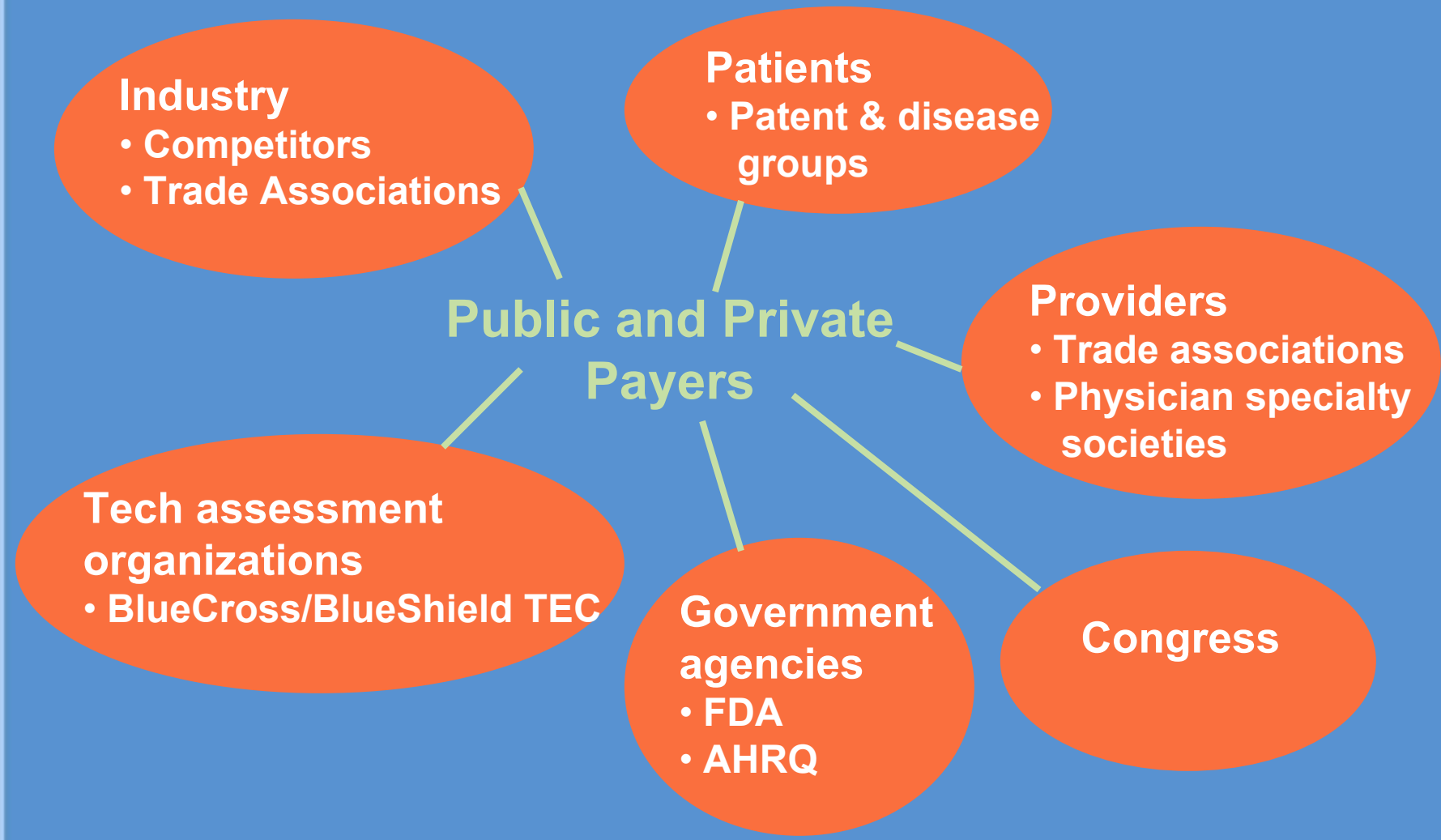
External Advocacy



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Internal Reimbursement Process

Establish multi-functional reimbursement team

Begin strategy development at R&D stage

Integrate reimbursement strategy activities throughout product life cycle

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Reimbursement Integration

R & D	Clinical Trials	Regulatory Approval	Product Launch
✓Perform initial reimbursement assessment	✓Assess clinical/ economic data needs	✓ Coordinate regulatory and reimbursement strategies	✓ Continue efforts to obtain codes and higher payment
✓ Reimbursement "due diligence"	✓ Collect data in trial	✓ Begin implementation of actions to obtain new codes/higher payments	✓ Seek coverage by payers
✓ Form reimbursement team	✓ Provide reimbursement support to trial centers		✓ Provide customer support
✓ Develop comprehensive strategy			

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Reimbursement Integration

Form multi-functional integration team(s)

Develop reimbursement SOPs

- Process
- Responsibilities

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Keys to Success

Demonstrate clinical and economic value

Obtain stakeholder support

Internal process integration

Adequate staffing and resources

- Benchmark competitors

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