REQUIREMENTS FOR REIMBURSEMENT OF NEW DEVICE TECHNOLOGIES

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Presented by:

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Mike is an experienced reimbursement consultant who specializes in providing strategic assessment and planning and tactical support to medical device clients across all payer and provider types. With over 17 years of experience working for medical device companies, he is particularly knowledgeable in supporting cardiac, peripheral vascular, neuromodulation, orthopedic and various other medical device therapy areas. Additional expertise includes helping medical device companies navigate Medicare's complex requirements for appropriate coverage, coding and payment in Category B Investigational Device Exemption (IDE) studies to help ensure timely enrollments in industry-sponsored clinical trials. Mike is also a veteran of the U.S. Air Force, holds a Master's degree from the College of St. Scholastica, and is a Certified Coding Associate (CCA) through the American Health Information Management Association (AHIMA).

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An experienced reimbursement consultancy providing expert strategy, analysis and support to medical device, diagnostic and clinical research clients. We provide the reimbursement knowledge and advice for our clients to successfully commercialize medical devices in the United States.

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TOPICS

- Define Reimbursement
- Coverage, Coding and Payment Systems
- Reimbursement Assessment of New Technologies
- Strategy Development and Planning
- Wrap-up/ Q&A

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REIMBURSEMENT: WHAT IT ISN'T?

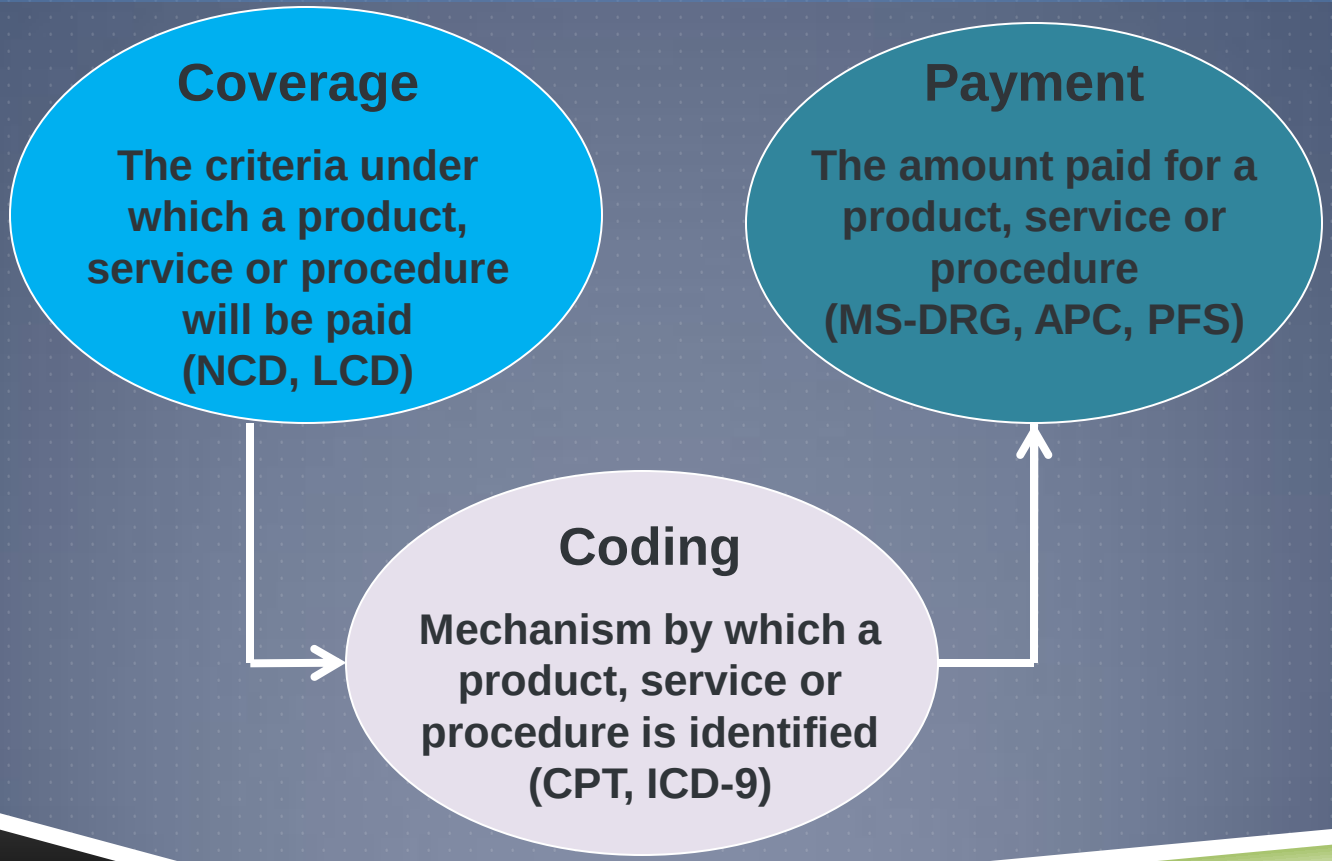
- **Something to think about just before product launch**
  - Best performed at concept and then carried forward throughout the product lifecycle
- **Considered at concept and then just left alone**
  - The external reimbursement landscape is in constant flux and must be continuously monitored
- **Less important than other internal assessments**
  - The stakes are high and have equal importance to other cross-functional assessments and strategic planning efforts!!!

Any gaps or delays in the coverage, coding, or payment landscape has a direct impact on new product adoption

WHAT IS "REIMBURSEMENT"?

- Three distinct elements: Coverage + Coding = Payment

ALL 3 are needed to ensure successful reimbursement!



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UNITED STATES

The U.S. healthcare system, a blend of multiple public payers and private third party payers, represents a manufacturer's largest market opportunity for most products and has the most stakeholders impacting the reimbursement process…

Manufacturers must understand the payer mix for their product...to assure that the reimbursement strategy aligns to the particular payer sector that will be the most prominent decision-maker.

Source: Global Trends in Reimbursement of Medical Technology (Clinica Reports, CBS948, July 2007):

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THE CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- CMS administers the Medicare and Medicaid programs, which provides health care to almost one in every three Americans.
- Medicare provides health insurance for more than 44.6 million elderly (≥ 65 years) and disabled Americans.
- Medicaid program provides health coverage for some 50 million low-income persons, including 24 million children, and nursing home coverage for low-income elderly.

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COVERAGE

The vast majority of Medicare coverage policy is determined on a local level by the contractors that pay Medicare claims (i.e., not by local or national coverage determinations but on a per-claim basis).

For any item to be covered by Medicare, it must first:

- be eligible for a defined Medicare benefit category;
- be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member; and,
- meet all other applicable statutory and regulatory requirements.

FDA Approval as "Safe & Effective" does not guarantee CMS Coverage as "Reasonable & Necessary"

Source: Innovators' Guide to Navigating Medicare (Version 2.0, 2010):
http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5_10_10.pdf

CODING SYSTEMS OVERVIEW

ICD-9-CM codes consists of codes for diagnoses and for hospital inpatient procedures.

- **Volume 1 contains the diagnosis codes** that every health care provider needs for billing (Note: Volume 2 is an alphabetical index of Volume 1).
- **Volume 3 contains procedure codes**, which are used for billing inpatient hospital stays in the Medicare Severity-Diagnosis Related Group (MS-DRG).

A new and much different "ICD-10" coding system is scheduled for implementation on Oct. 1, 2014

CODING SYSTEMS OVERVIEW

CPT-4® codes: Used to describe both physician (all service sites) and "outpatient" hospital services:

- The two main types of CPT codes include Category I (Permanent) codes and Category III (Emerging technology) codes
  - If no existing CPT code matches a new service, then providers must use "unlisted" codes **"Close to" is not good enough**

Level II HCPCS codes: Level II HCPCS codes are used primarily to identify products not included in the CPT codes:

- Such as drugs and biologicals, or durable medical equipment (E.g., Device Product Category "C-codes")

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MEDICARE PAYMENT

Once coverage and coding are established, Medicare payment is assigned depending on the provider type and site-of-service.

- Medicare pays for most items and services on a prospective payment basis (E.g., not at cost but at fixed average amount)

Medicare Payment System Summary:

1) Medicare-Severity Diagnosis Related Groups (MS-DRG)

- Specific to Inpatient hospital admissions under IPPS
- One bundled payment per admission based on patient conditions, severity of conditions, and procedures performed

Source: Innovators' Guide to Navigating Medicare (Version 2.0, 2010):
www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5_10_10.pdf

MEDICARE PAYMENT

2) **Ambulatory Payment Classifications (APC)**
   - Specific to outpatient hospital encounters
   - One or more payments per encounter based on number the of procedures performed
   - Subject packaging rules and multiple procedure discounting
3) **Physician Fee Schedule (PFS)**
   - Specific to professional provider services (All sites of service)
   - One or more payments per encounter based on the number of procedures performed

Source: Innovators' Guide to Navigating Medicare (Version 2.0, 2010): www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5_10_10.pdf

REIMBURSEMENT ASSESSMENT

1. Provides a baseline analysis of potential reimbursement gaps, risks, and opportunities for new devices beginning at concept
   - Strategy (e.g., funding decisions)
   - Diligence (e.g., potential sale/purchase of IP)
2. Promotes timely cross-functional decision-making
   - Do not assume someone is taking care of it!
3. Integrates strategic reimbursement deliverables into key product development milestones
   - Reimbursement execution is often dependent on regulatory milestones and publication timelines

ASSESSMENT KEY ELEMENTS

1. **Identify competing products and clinical trials**
   - Is there comparable device on the market?
   - Who will be first to market? When? (clinicaltrials.gov)
     - First to market often paves the reimbursement path
2. **Determine reimbursement gaps, risks, and opportunities**
   - What is the current coding/coverage/payment landscape?
     - What changes to this landscape are anticipated?
   - What's the anticipated "payer mix"? (e.g., Medicare, private, Medicaid, Workers Comp., others?)

ASSESSMENT KEY ELEMENTS

3. **Develop strategies to address gaps, mitigate risks, and leverage opportunities**
   - What clinical data needs to be generated and published?
   - What cost data needs to collected and by who?
   - What resources need to be budgeted and planned for?

REIMBURSEMENT PLANNING

Create a Reimbursement path for success based on the assessment findings...

- A reimbursement assessment is only as good as the planning and execution that can come from it
- Internal planning is tough, but missing a key reimbursement milestone is even worse, for example:
  - 18-24 month delay in new or revised CPT coding
  - Inadequate clinical data to influence payers
  - No cost data to demonstrate economic value to customers
  - Payment levels that do not reflect to cost of the technology

WRAP-UP

Thank you!

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