MEDICAL DEVICE REIMBURSEMENT

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TOPICS

- U.S. Healthcare System Overview
- Coverage Policy, Coding/ Payment Systems
- Reimbursement Assessment of New Technologies
- Strategy Development/ Planning
- Wrap-up/ Q&A

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):

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.

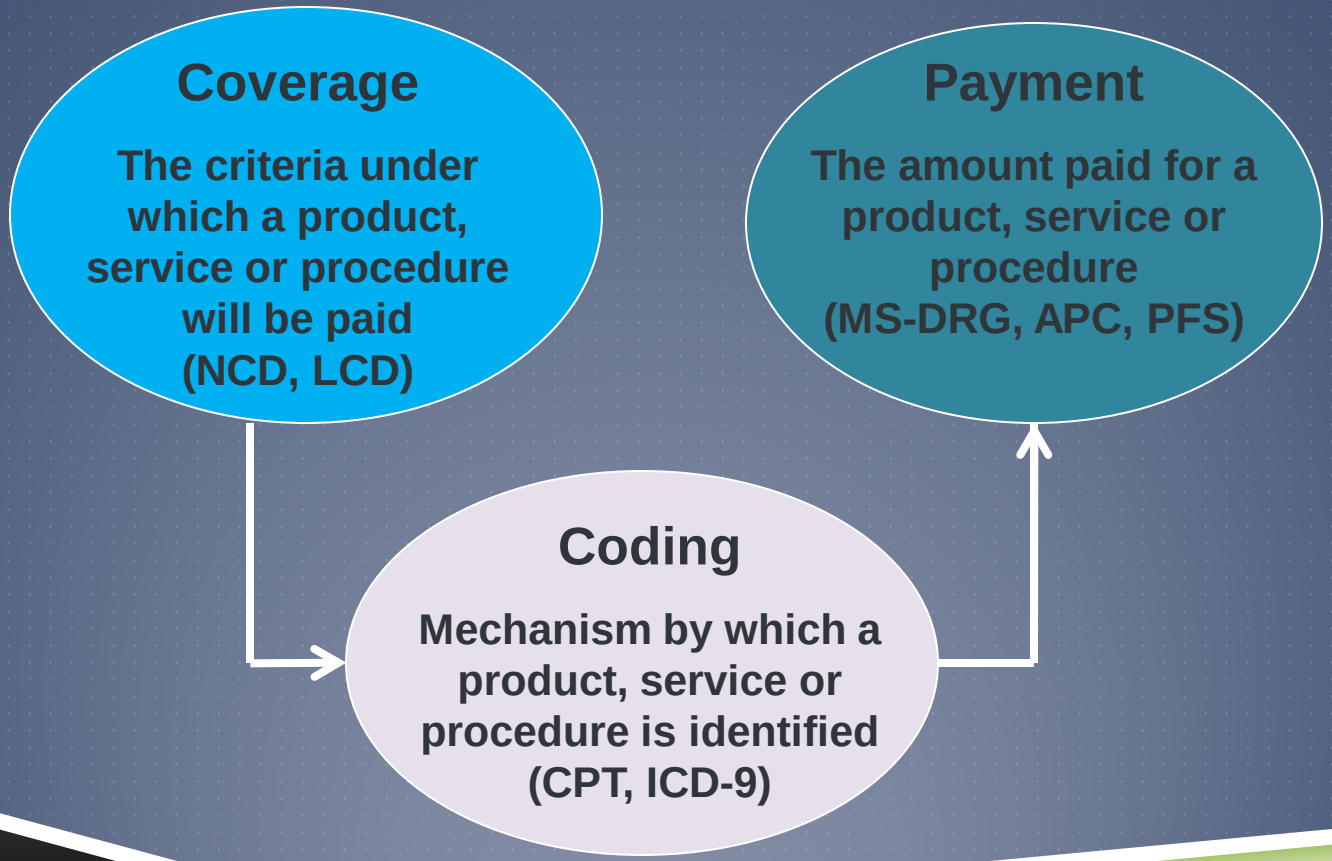
U.S. REIMBURSEMENT SYSTEMS OVERVIEW

- The key components for successful Medicare and commercial payer reimbursement include Coverage, Coding and Payment
- All three of these elements are essential if adequate reimbursement is to be obtained for a new medical device technology.
  - For example*, just because a discrete code is available, it does not mean a procedure will be covered or paid appropriately*.

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

WHAT IS "REIMBURSEMENT"?

- Three distinct elements: Coverage + Coding = Payment



8

COVERAGE

The vast majority of coverage policy is determined on a local level by the Medicare contractors that pay Medicare claims (i.e., not by written coverage policy 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 Medicare statutory and regulatory requirements.

FDA approval does not guaranty CMS coverage

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

CMS NATIONAL AND LOCAL COVERAGE

National Coverage Determination (NCD)

- In certain cases, Medicare deems it appropriate to develop criteria for coverage via a national coverage determinations

Local Coverage Determination (LCD)

- Medicare administrative contractor (MAC) develops Local Coverage Determination that apply only within the jurisdiction served by the individual contractor.

CODING SYSTEMS OVERVIEW

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

- **ICD-9-CM Volume 1 contains the diagnosis codes** that every health care provider needs for billing (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).

Note: *a new and much different ICD-10 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
  - "Close to" is not good enough -- If no existing CPT code matches a new service, then providers must use "unlisted" codes

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

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

MEDICARE PAYMENT

Hospital Payment Systems

- Once coding and coverage are established, hospital payment is assigned depending upon the site of service the procedure is performed.

Physician Payments

- Physicians are paid on a per-procedure basis, as indicated using CPT codes.
- Each CPT code has a relative weighting from which the reimbursement amount can be derived.

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

MEDICARE PAYMENT

Medicare pays for most items and services on a prospective rather than cost basis. A prospective, fixed payment system allows for better resource planning by providers, offers bundled services or items for care management, and provides incentives for efficiencies.

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 of procedures performed
   - Subject packaging rules and multiple discounting
3) **Physician Fee Schedule (PFS)**
   - Specific to professional provider services (All sites of service)
   - One or more payments per encounter based on 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: WHAT IS ISN'T?

- **Something to think about just before product launch**
  - Assessment best performed at concept then carried forward throughout the product lifecycle
    - The external reimbursement landscape is in constant flux and must be continuously monitored from *concept on through market maturity*
- **Less important than other 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

REIMBURSEMENT STRATEGY

1. **Identify competing products**
   - Are there comparable devices on the market?
   - Who will be first to market? When? (clinicaltrials.gov)
     - First to market company tends to pave the reimbursement landscape
2. **Determine reimbursement gaps, risks, and opportunities**
   - What is the current coding/coverage/payment landscape?
   - What changes to this landscape are anticipated?
     - E.g., The Accountable Care Act (aka Obama-Care)
   - Is there potential value to the healthcare system
     - E.g., more effective/ less expensive

REIMBURSEMENT STRATEGY

3. **Develop internal strategies to address gaps, mitigate risks, and leverage opportunities**
   - What data needs to generated or collected and when?
     - E.g., Cost and utilization data during pivotal trial
   - What internal resources will be needed and planned for?
     - E.g., Dedicated team and budget
   - What outside support support is required?
     - Consulting expertise often needed to change reimbursement

QUESTIONS?

Thank you!

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