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
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.

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.
The key components for successful Medicare and third-party 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.

WHAT IS “REIMBURSEMENT”? 

- Three distinct elements 

  Coverage 
  The criteria under which a product, service or procedure will be paid (NCD, LCD) 

  Coding 
  Mechanism by which a product, service or procedure is identified (CPT, ICD-9) 

  Payment 
  The amount paid for a product, service or procedure (MS-DRG, APC, PFS)
COVERAGE + CODING = PAYMENT

Coverage
Reasonable and necessary
National determinations
Local determinations

ICD-9-CM diagnosis codes
Why patient received treatment

CPT HCPCS procedure codes
How patient received treatment

Fee schedule payment
(physician)

APC payment
(outpatient hospital)

DRG payment
(inpatient hospital)
Coverage

- FDA approval does not guarantee Medicare Coverage.

- Medicare makes National Coverage Determinations (NCDs) for specific procedures or services that apply to all contractors throughout the country.

- Local Medicare Contractors make Local Coverage Determinations (LCD) that are applicable to their geographic region only.

- National Coverage Determinations supersede Local Coverage Determinations.

- CMS - “Reasonable & Necessary”

- FDA - “Safe & Effective”
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.

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 develops Local Coverage Determination that apply only within the jurisdiction served by the individual contractor.
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
- 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., C-codes)
CODES USED VARY BY PROVIDER TYPE/PLACE OF SERVICE
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.

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

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

WHY IS PERFORMING A REIMBURSEMENT ASSESSMENT IMPORTANT?

1. Provides a baseline analysis of potential reimbursement gaps, risks, and opportunities for new devices therapies
2. Promotes timely informed decision making that includes formal analysis of potential reimbursement pitfalls and opportunities
3. Integrates strategic reimbursement deliverables into key internal product development processes and timelines

Any gaps or delays in the coverage, coding, or payment landscape has a direct impact on new product adoption
REIMBURSEMENT ASSESSMENT: WHAT IS ISN'T?

- **Something to start thinking about just before product launch**
  - Best performed at concept in partnership with R&D and strategic marketing and then carried forward throughout the product lifecycle

- **Done at concept and then just left alone**
  - External reimbursement landscape is in constant flux; Baseline assessment must be continuously monitored and adjusted from concept on through market maturity

- **Less important than other assessments**
  - Don’t Assume! Must have equal importance to other internal assessments and during strategies planning
1. Identify competing products and clinical trials
   - Is there comparable device on the market?
   - Who will be first to market? When? (clinicaltrials.gov)

2. Determine reimbursement gaps, risks, and opportunities
   - What is the current coding/coverage/payment landscape?
   - What changes to this landscape are anticipated?
   - Is there potential value to the healthcare system (e.g., more effective & less expensive)
REIMBURSEMENT ASSESSMENT KEY ELEMENTS

3. Develop internal strategies to address gaps, mitigate risks, and leverage opportunities
   ▶ What data needs to be generated or collected and when?
   ▶ What internal resources will be needed and planned for?
   ▶ What outside assistance or support is required?
Questions?
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Committed to helping your company make intelligent, informed decisions that includes sound reimbursement advice

- PRC is an experienced reimbursement consultancy providing expert strategy, advice and support services to medical device, diagnostic and clinical research clients