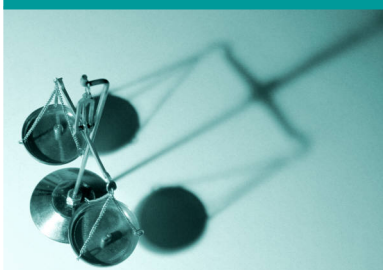


ADVAMED 2007

THE MEDTECH CONFERENCE

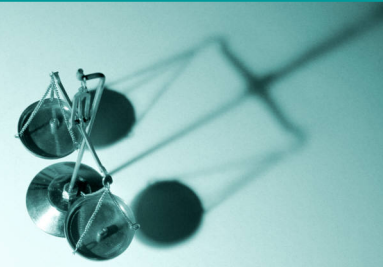
October 1-3, 2007

Washington, D.C.



**We Made It! Will Medicare Pay? And How Much?:
Medicare Coverage and Reimbursement Issues
Affecting Medical Device Manufacturers**

Robert L. Roth, Esquire
Crowell & Moring LLP
1001 Pennsylvania Ave., NW
Washington, DC 20004-2595
Tel: 202-624-2870
Fax: 202-628-5116
rroth@crowell.com



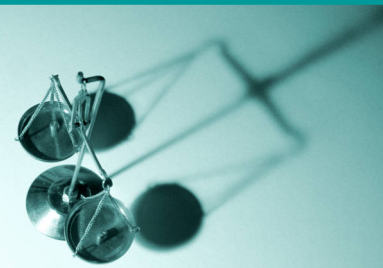
Overview of Session

Panelists:

- Marcel E. Salive, MD, MPH, Director, Division of Medical & Surgical Services, OCSQ/Coverage & Analysis Group, CMS
- Brent O'Connell, MD, MSHSA, Argenta TEC
- Ms. Susan L. Kelly, Director of Reimbursement, DePuy Spine

Moderator:

- Robert L. Roth, Esq., Crowell & Moring LLP



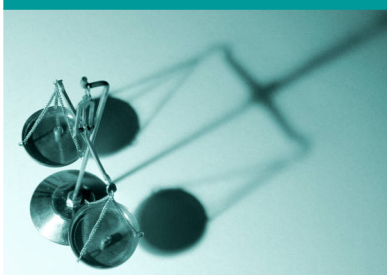
Overview of Session

In order to understand how Medicare pays for medical devices, it is important to understand the interlocking meaning of, and the different processes relating to:

Coverage

Coding

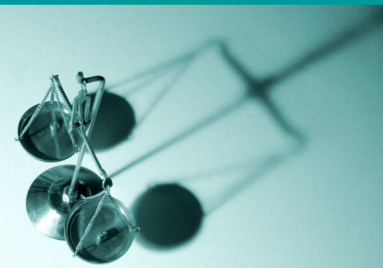
Payment



Overview of Session

**The irresistible force of innovation
pitted against the immovable object of
government regulation.**

- The Government always wins
- Medicare can influence other payers
- Better understanding of the processes will allow for better planning and less frustration
- Coverage, coding, and payment isn't everything

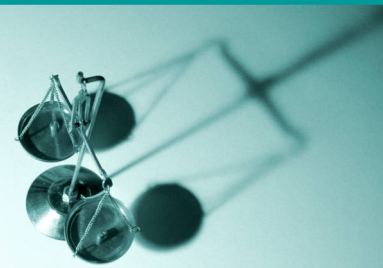


Overview of Session

Goal for this Session

Enhance understanding of strategies that can be used to achieve proper Medicare payment through explanation of:

- How coverage, coding, and payment combine to determine Medicare payment amount
- How the coverage, coding, and payment processes work
- The importance of developing a strategy and putting together a multi-disciplinary team



Overview of Session

COVERAGE

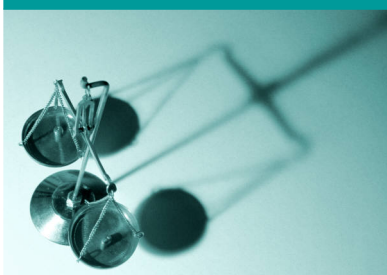
- Established and not excluded by statute
- “reasonable and necessary”
- FDA approval does not guarantee coverage
 - FDA - safe and effective for marketing
 - CMS – reasonable and necessary
- Focus is on CMS
- Coverage does not assure particular code or payment level



Overview of Session

COVERAGE PROCESSES

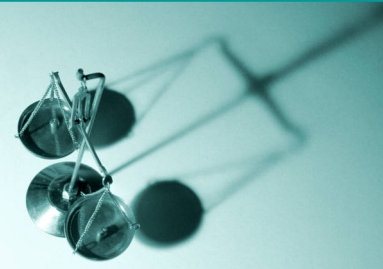
- National Coverage Determinations (“NCDs”) – binding on Medicare contractors, Medicare Advantage Plans, ALJs, etc.
- Process for adoption
- Medicare Evidence Development Coverage Advisory Committee - MedCAC



Overview of Session

COVERAGE PROCESSES

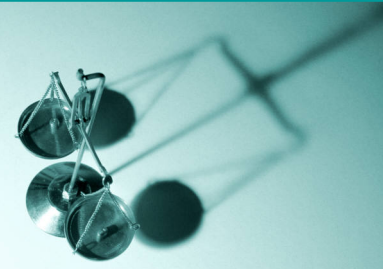
- Local Coverage Determinations (“LCDs”) – apply where no NCD, statute, or regulation
- Discretion of Medicare Administrative Contractor
- Apply Contractor-wide
- Process for adoption
- Historical Distinction - LCDs vs. Local Medical Review Policies (“LMRPs”)



Overview of Session

COVERAGE PROCESSES

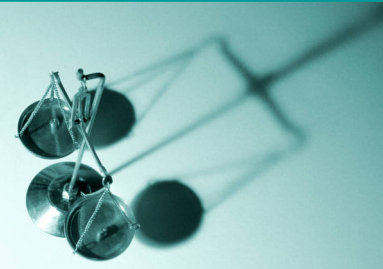
- Medicare Coverage Database – contains NCDs and LCDs
- <http://www.cms.hhs.gov/mcd/search.asp>



Overview of Session

CODING

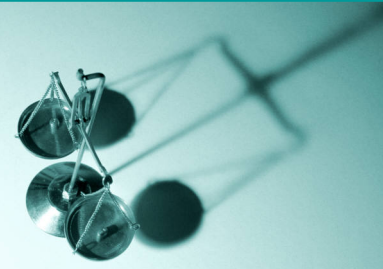
- Bridge from Coverage to Payment
- Does not assure coverage or favorable payment determination
- Identifies drug, device, diagnosis, or procedure



Overview of Session

CODING

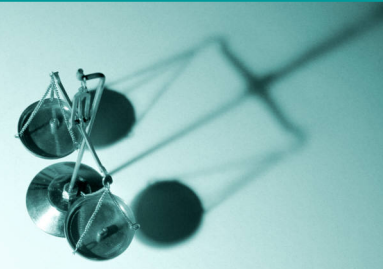
- HCPCS – procedures, drugs, devices
 - Level 1 – CPT - medical services and procedures - maintained by American Medical Association
 - Level 2 – CMS – “standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office.”
- ICD-9-CM – inpatient hospital procedures



Overview of Session

CODING PROCESSES

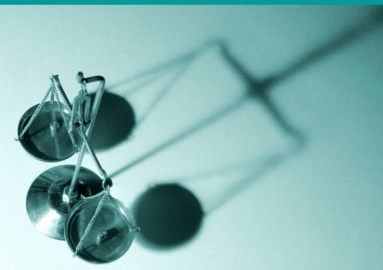
- HCPCS, CPT, ICD-9 - Each has its own process for adoption
- Need to be aware of time periods to request new codes or change to existing codes
- Role of SADMERC



Overview of Session

MEDICARE PAYMENT

- Must be covered
- Must be “reasonable and necessary”
- Must be for a Medicare-eligible individual
- Medicare must be primary
- Site of service matters
- Part A vs. Part B vs. Part C vs. Part D



Overview of Session

MEDICARE PAYMENT SYSTEMS:

Inpatient Hospital PPS – Part A

Outpatient Hospital PPS – Part B

Physician Fee Schedule – Part B

Ambulatory Surgery Centers – Part B

Laboratory – Part B

Durable Medical Equipment – Part B

Prescription Drugs – Parts B and D

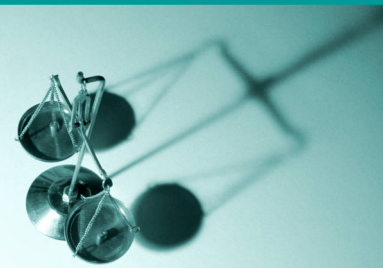
All of the Above – Part C



Overview of Session

MEDICARE PAYMENT PROCESSES

- Each payment system has its own processes for adoption and modification
- Need to be aware of the timing of each



Overview of Session

Other Issues

- Investigational Devices
- Off-Label Use
- Clinical Trials Policy
- Services related to Non-Covered Device
- Beneficiary appeals of payment/coverage denials
- “Least costly medically-appropriate alternative”/
functional equivalence

4221837.2