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Update on Coverage, Coding and Reimbursement for Medical Devices Domestically, Including Case Studies



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Agenda

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- Basic Concepts of Coverage, Coding and Reimbursement
- New Developments
- Case Studies

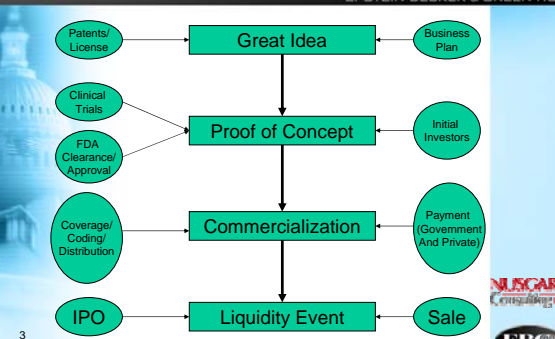
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Critical Milestones In Product Commercialization

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graph TD
    GI[Great Idea] --> PC[Proof of Concept]
    PC --> C[Commercialization]
    C --> LE[Liquidity Event]
    
    PL((Patents/License)) --> GI
    BP((Business Plan)) --> GI
    
    CT((Clinical Trials)) --> PC
    FDA((FDA Clearance/Approval)) --> PC
    II((Initial Investors)) --> PC
    
    CCD((Coverage/Coding/Distribution)) --> C
    IPO((IPO)) --> LE
    PGP((Payment Government And Private)) --> C
    S((Sale)) --> LE
  
```

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Three Distinct Concepts

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Coverage – Terms and conditions for payment

- Is not guaranteed when you receive FDA approval/clearance
- Does not guarantee a new or favorable billing code
- Does not guarantee favorable reimbursement


Coding – Identifiers

- Links coverage and payment
- Does not guarantee coverage
- Does not guarantee favorable reimbursement

Payment – Remuneration

- Function of coverage and coding
- May be subject to limits
- May be stand-alone or bundled
- May be driven by breakthrough or existing technologies

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Who Are The U.S. Payers?

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<p>Private Payers</p> <ul style="list-style-type: none"> Employers <ul style="list-style-type: none"> - self-funded or not Unions/Taft-Hartley Health Plans <ul style="list-style-type: none"> -Blue Cross/Blue Shield Plans -United Healthcare -Aetna US Healthcare -Anthem Wellpoint -Others -Third Party Administrators 	<p>Public Payers</p> <ul style="list-style-type: none"> Medicare <ul style="list-style-type: none"> -federal -seniors, disabled, ESRD Medicaid <ul style="list-style-type: none"> - federal/state - indigent, women, children, indigent seniors, chronically ill SCHIP <ul style="list-style-type: none"> - federal/state - children TriCare <ul style="list-style-type: none"> - federal - military dependents FEHBP Others
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Coverage and Payment Concepts

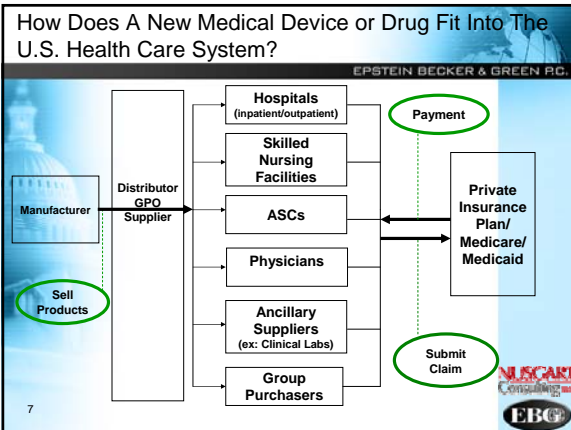
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General Rule:
Coverage and Payment of Devices and Drugs
Depend upon:

1. Site of Service
2. Enumerated Benefits
3. Enumerated Exclusion
4. Coverage determinations (nationally/locally)

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- ### Achieving Coverage
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- Coverage Requests
- product manufactures
 - patients/advocacy organizations
 - Physicians
- Coverage Decision Makers
- medical directors of plans
 - Human resource professionals
 - P&T Committees
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- ### Decision Process of Payers
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- | | |
|---|--|
| <p>Clinical Issues</p> <ul style="list-style-type: none"> • Safety • Efficacy • Outcomes • Appropriate for plan's patients • Impact on current treatment option • Analysis by technology assessment groups | <p>Non-Clinical Issues</p> <ul style="list-style-type: none"> • Utilization • Financial impact • Coverage by other payers (both private and public) • Legal • "Head line test" • State mandate • Publicity • Demand |
|---|--|
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The Use of a Centralized Council Within the Payer or Independent of the Payer

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- Performance of systematic reviews of existing research
- Perform technology assessment
- Focus on clinical evidence and cost effectiveness data
- Identify gaps in knowledge
- Provide information in easily utilized data base format
- Provide ongoing continuous assessment

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Example:
BCBSA Technology Assessment

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- Must have approval of governmental agency such as FDA
- Scientific evidence that permits conclusion on effectiveness through clinical trials with human subjects that are appropriately designed and have adequate control group
- Must have positive effect on health outcomes
- Must be at least as beneficial as the "standard of care" alternatives
- Must have proof that the above outcomes can be seen outside of investigational setting

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Where Does the Evidence Come From

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- Scientific peer reviewed journals (Preferably US based)
- Specialty Society guidelines or consensus statements
- Cochrane reviews
- Independent technology assessment reviews (Hayes, Milliman, ECRI)
- Independent consultants
- Internal Medical and Pharmacy Directors

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Two Views of Evidentiary Data

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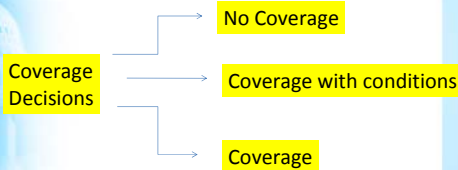
Payer	Industry
<ul style="list-style-type: none"> • Head to head design • Large diverse populations • Diverse settings • Long term follow up • Considers natural history of the disease 	<ul style="list-style-type: none"> • Feasibility of the trials • Costs to the trials • Scalability of trials • Time to market

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Coverage Decision Tree

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Regardless of the payer, the bar is being set to a higher level

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“The agency is being clear that in order to get coverage or adequate payment, we’re going to be looking for high-quality scientific evidence, including head-to-head clinical trials that incorporate meaningful outcomes. The intent is to incentivize the conduct of that sort of study”

Sean Tunis, Former Chief Medical Officer, CMS 2003

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Coding Basics

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TYPES OF CODES

- ICD-9-CM*: Diagnoses & Inpatient Hospital Procedures
- CPT: Procedures
- HCPCS: Drugs and Devices

*ICD-10-CM is coming shortly

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Coding Basics

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Key Coding Issues for Billing Codes: Similar to coverage issues

- Site of service
- Financial implications
- Professional v. Technical Components
- CPT Codes versus HCPCS Codes
- Related procedure codes for devices

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How Is a New CPT Code Developed?

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graph TD
    A[Manufacturer/Specialty Society with an idea] --> B[CPT Editorial Panel Staff Review]
    B --> C[CPT Specialty Advisors]
    C --> D[CPT Editorial Panel]
    D --> E[Reject Application]
    D --> F[Table Application]
    D --> G[Approve New CPT Code and Refer to RUC]
  
```

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Coordinating Coverage With Coding & Payment

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- Coverage determinations can have an impact on coding and payment
- Analysis of competing or similar devices in the same coding category:
 - What are the codes used for those devices?
 - What is the range of payment?
 - Is the prevailing payment range acceptable?
 - If not, what evidence justifies either a new code or higher payment?

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Where Does Coding for Medical Device Billing Fit?

Payer

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    graph LR
      FDA[FDA Safe and effective?] --> Coverage[Coverage Reasonable and necessary?]
      Coverage --> Reimbursement[Reimbursement How much should we pay?]
      Reimbursement --> Patient[Patient]
      Patient --> Post[Post approval]
      Coding[Coding How can we identify it?] --> Reimbursement
  
```

Coding:

- Where will it be used? Hospital, doc's office, outpatient?
- Which coding system applies?
- Does a code already exist?
- Do you need a new one? (Be ready for a long, complex journey)

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Where Does Coding for Medical Device Billing Fit? (cont.)

- Manufacturers LIVE AND DIE by BILLING CODING
- By establishing appropriate code for billing a product/identify payment levels
- If placed in code that does not include like products, the reimbursement and claim could be inappropriate

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Coding Systems - HCPCS

- Devices may be used in a variety of settings, such as hospitals, physician offices, and patient homes
- CPT codes describe professional services
- HCPCS codes describe the device used in connection with a professional service

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Coding Strategy for Medical Devices

- Does it have FDA approval yet?
- Where will it be used?
- Which coding system applies?
- Does a code already exist? Can it fit under this already existing code?
- Does it need a new code?

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Coding Verification – Who is the PDAC?

- Medicare Pricing Data Analysis and Coding
- Used to be the SADMERC until 2008
- Located in Fargo, North Dakota
- Part of Noridian Administrative Services
- Offers guidance on proper use of HCPCS; advisor to HCPCS Workgroup for new coding decisions
- Performs national pricing functions; assists CMS on fee schedules
- Offers online Durable Medical Equipment Coding Center and call center for providers


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Why Do You Need Coding Verification For Your Product?

- Marketing and Compliance reasons - Products that are code verified will appear on PDAC website under Product Classification Lists
- Payer reasons - Some Medicaid's want to see PDAC letter to show that product falls under certain HCPCS code
- Strategy for getting new code - if PDAC gives you miscellaneous codes, it shows that no other code describes your product

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Coding Verification Request

- PDAC product specific application
- 90-day timeframe
- Submit at any time
- 877.735.1326
- Applications found at: <https://www.dmepdac.com/review/index.html>


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New HCPCS Code Process/Timetable for 2009-10 Coding Cycle

- Application submitted to CMS before Jan. 4, 2010
- One year timeframe
- Decisions in Nov. 2009-Implemented in Jan. 2010
- Decisions made by CMS HCPCS workgroup panel (composed of the Medicaid, CMS) The PDAC and Private Payor Representatives act as Consultants

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For a New CPT Code – The Process

- Very political process
- Needs a physician specialty association to submit application on your behalf
- Application must be carefully written by someone who is knowledgeable on knowing how to present the important information
 - Needs cover letter along with application
 - Clinical vignette is most important since it forms the basis on how much the procedure will be reimbursed later in the CPT process

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For a New CPT Code – The Process (cont.)

- You and the physician specialty association will need to lobby other specialty associations who are part of the AMA CPT Advisory Committee to support your submission
- Specialty association representative will present the request at AMA meeting
- If code approved, then will undergo process to determine reimbursement
 - <http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes/request-form-category-ii.shtml>

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Timetable for New CPT Code

- For 2011 coding year - implemented January 1
- 2009 submission deadlines - March, July, November
- Corresponding CPT meetings - June 2009, October 2009, February 2010
- RUC Meetings to determine payment - October 2009, February 2010, April 2010

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How to Set the Stage for Successful CPT and HCPCS Coding Decisions

- CPT
 - Education and Involvement/Endorsement of Professional Societies is the Key
 - Write an appropriate clinical vignette that addresses the complexity of work involved since that corresponds to payment
- HCPCS
 - Make the CMS staff and DME MAC medical directors your NEW BEST FRIENDS – Go Visit Them! (before you submit application and after you have received your CMS coding letter in November)
 - HCPCS Application - Follow Directions, Submit Peer Reviewed Published Studies
 - If attend HCPCS Public Meeting - Bring Physicians or Clinicians as Advocates; It is not a sales presentation!
 - It is OK to Resubmit Application for the next year

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General Payment Methodologies

For example, with the Medicare Program:

- DRGs, APCs, Reasonable Costs
- Fee Schedules
- Average Sales Price

For example, with Other Payers:

- Per Diems
- Case Rates, Global Payments

Sometimes, payment rates are a derivative or percentage off of a published fee schedule.

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What's New in Coverage?

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- American Recovery and Reinvestment Act of 2009
 - Authorized \$1.1 billion for Comparative Effectiveness Research
 - HHS required to appoint 15-person Federal Coordinating Council
 - The Council is forbidden by law from recommending clinical guidelines for payment, coverage, or treatment
 - Agency for Healthcare Research and Quality (www.ahrq.gov)

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What's New in Coverage? CMS-MedCAC-AHRQ-HTAs

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Coverage with Evidence (CED) Cases, 1999-2007

Technology	Date of Decision	Notes	Status
Lung volume reduction surgery (LVRS)	2003	From 1996 to 2003, CMS covers LVRS only within an NIH-sponsored RCT. ultimately, CMS covers LVRS only for types of patients who benefit and only in approved facilities; use of LVRS falls after NCD	Trial published in 2003 Use of LVRS falls after trial
Positron-emission tomography (PET) for suspected dementia	2004	CMS covers FDG-PET for patients with suspected dementia only for patients enrolled in a "large practical clinical trial"	Trials ongoing
PET for cancers	2005	CMS expands coverage of PET for cancer to situations where providers and patients are enrolled in a prospective data collection system. CMS identifies National Oncologic PET Registry as meeting such system requirements	Registry ongoing
Implantable cardioverterdefibrillators (ICDs)	2005	CMS covers ICDs for subgroup while primary prevention indications are subject to prospective data collection in an ACC National Cardiovascular Data Registry	Registry ongoing with collection of longitudinal data in the development phase
Chemotherapy for colorectal cancer	2005	CMS covers off-label use of chemotherapy drugs for colorectal cancer for patients enrolled in NCI-sponsored RCTs; local contractors may cover off-label uses at own discretion	NCI trials ongoing
Cochlear implantation	2005	CMS expands coverage for patients with less severe hearing loss based on participation in RCT	No proposals for trials emerged in response to NCD
Home use of oxygen	2006	CMS expands coverage for home use of oxygen to less severely impaired patients enrolled in an NHLBI-sponsored RCT	Trials under way

34 Source: Health Affairs, November/December 2008 located at <http://www.healthaffairs.org>



What's New in Coverage? Trends in CMS National Coverage Determinations

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- Between 2000 and the first quarter of 2008, CMS issued 133 NCDs, of which 39 Were Reconsiderations.
- Majority of the NCDs and reconsiderations (72 percent) were issued between 2004 and 2006.
- More recently, there were 27 NCDs and Reconsiderations during 2007 and Q1, 2008.
 - 18 were internally generated by CMS
 - 8 were generated by manufacturers
 - 6 were generated by providers
 - 1 was generated by a carrier
 - 1 was generated by Joint Commission

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What's New in Coverage? Trends in CMS National Coverage Determinations

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- Clinical Topics cover wide range of clinical areas including cardiothoracic surgery, neurosurgery, oncology and immunology
- Benefit Categories cover wide range of benefit categories including physician services, DME, screening and diagnostic tests and Part B covered drugs
- PTA/Stent procedures have been the topic of six reconsiderations

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What's New in Coverage?
 MedCAC Top Ten Priorities: Predictor of Future Trends in NCDs?

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- 4 of MedCAC's Top Ten Priorities Related to Oncology:
 - Appropriate ESA use in cancer patients
 - Benefit of cancer prognostic markers OncoDX, Her-2-Neu
 - Benefits of high cost cancer drugs
 - New Radiation treatments for cancer: IMRT, proton beam
- 2 of MedCAC's Top Ten Priorities Related to Neurology:
 - Comparative effectiveness of the treatment of carotid artery disease
 - Comparative effectiveness of the treatment of acute stroke (i.e., clot retrieval vs. reperfusion drugs)
- 4 of MedCAC's Top Ten Priorities Related to:
 - Treatment of atrial fibrillation
 - Benefit of early aggressive treatment of diabetes
 - Comparative effectiveness of treatment of ulcers (i.e., off-loading, debridement, biologics, revascularization)
 - Appropriate use of hospice care
- Upcoming MedCAC- Nov 18- Secondary Lymphedema

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What's New in Coverage?
 MedCAC Top Ten Priorities: Predictor of Future Trends in NCDs?

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- Comparative Effectiveness is Listed Among MedCAC's Top Evidentiary Priorities for the Medicare Program
 - 4 topics relate to neurology
 - Including the two topics in the Top Ten Priorities
 - 3 topics are unrelated to a particular specialty:
 - Wound care treatments
 - Diabetes treatments
 - Bone density testing

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What's New in Coverage?
 Media Coverage of "Coverage"

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December 1, 2008	WSJ	"An Implant That Hits a Nerve"
December 2, 2008	NYT	"Cardiologists Debate Expensive Heart Scans"
December 3, 2008	NYT	"British Balance Benefit vs. Cost of Latest Drugs"
December 17, 2008	NYT	"Geography Has Role in Medicare Cancer Coverage"
December 30, 2008	NYT	"Patient's DNA May Be Signal to Tailor Medication"

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What's Otherwise New?

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- ECRI's Top 10 Technology Hazards that should be on every hospital's list of safety concerns for medical device use:

• Alarm Hazards	• Needlesticks and other sharps injuries
• Air Embolism from contrast media injectors	• Surgical fires
• Anesthesia hazards due to inadequate pre-use inspections	• Misleading displays
• CT radiation dose	• MR imaging burns
• Retained devices and unrestrained fragments left in patients	• Fiber optic light source burns

40 Source: ECRI Institute located at <http://www.ecri.org/>

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Concerns with HCPCS Coding Process- HCPCS Level II Code Tally

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CY	HCPCS Code Requests Submitted (O&P, DME, Supply)	New HCPCS Codes Granted
CY 2007	171	35
CY 2008	105	12
CY 2009	123	22
CY 2010 (prelim)	99	13

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Concerns with Current HCPCS Code Process

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- Current HCPCS code set – broadly defined codes
 - Ambiguous and Imprecise
 - Leads to improper payment accuracy for payers
 - "CMS Does not know what it is paying for"- MedPAC
 - Pay too much for basic; Pay too little for complex technology
 - Adverse impact on providers and patients

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Concerns with Current HCPCS Code Process (cont.)
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- Decision Making Process not Transparent, Predictable or Timely
 - Criteria used to justify new codes fluctuate and never been subject to notice and comment
 - Subjective definitions of what is needed to obtain a new code; threshold is escalating
 - Who are the Decisionmakers? -No published listing; stakeholders are excluded
 - No reconsideration process

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Concerns with Current HCPCS Code Process (cont.)
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- Decision making process improperly comingles Medicare coverage with coding decisions
 - Coding determinations often include review of clinical evidence similar to info used to determine coverage decisions
 - Using Medicare coding criteria usurps other payer's ability to establish own coverage policies
 - Ignores key intents of universal code set-identify same products –simplify billing and claims processing

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Alliance for HCPCS II Coding Reform
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- Formed in May 2008 to seek improvements to the HCPCS Coding Process to make it predictable, transparent and accountable
- Comprised of key law firms, lobbying firms, associations, coalitions, medical device companies and reimbursement consulting companies with expertise in HCPCS coding who recognize the need to take action to reform the HCPCS coding system

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What's New in Payment?
Value Based Purchasing

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- CMS Not Paying Hospitals for “Never Events” (Hospital Acquired Conditions/Present on Admission)
- OIG Advisory Opinions on Gainsharing Between Hospitals and Physicians
- Competitive Bidding by CMS for Certain Durable Medical Equipment Used in the Home

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What's New in Payment?
CMS DMEPOS Competitive Acquisition (Bidding) Program

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- **Background:**
 - MMA required the HHS Secretary to establish a DMEPOS Competitive Bidding Program.
 - Competitive Bidding was to be phased-in and would replace the Medicare fee schedule.
 - CMS selected high volume/expenditure items and services
- **MIPPA delayed competitive bidding – until 2009**
 - Rule became effective April 17, 2009 despite the pleas of industry groups and 84 members of Congress to delay implementation
- **Payment tradeoffs include:**
 - 2009 Fee Schedule update reduced by 9.5% for all Round One items, services and accessories.
 - Reduction applies to all areas, not just competitive acquisition areas.
 - For items or services that were not part of Round One, the fee schedule update in 2009 will be the increase in the consumer price index (CPI) as required by law.

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What's New in Payment?
CMS DMEPOS Competitive Acquisition (Bidding) Program

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- **Payment tradeoffs include (cont.)**
 - For 2010 through 2013, the fee schedule update will be the increase in the CPI for all items and services outside competitive bidding areas.
 - For 2013 the update will be the increase in the CPI plus 2% for items and services that (1) had received a 9.5% reduction in 2009, (2) had not received a payment adjustment based on the Secretary's authority to adjust payments outside of competitive areas based on data from competitive bidding, and (3) were not part of a competitive bidding area.
 - For all others, the 2014 update will be the increase in the CPI.
- **Updates**
 - Rebids open Oct 21; sign up by Dec 21
 - Implementation Jan 2011
 - HR 3790- Eliminate Comp bidding introduced
- **Websites for more information:**
 - Competitive bidding:
http://www.cms.hhs.gov/DMEPOSCompetitiveBid/01_overview.asp
 - Competitive bidding Implementation contractor website:
<http://www.dmecompetitivebid.com>

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Case Studies

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Hearing Aid or a Prosthetic Device?

A Case Study

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Case Studies

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Low Profile Gastrostomy Tube

A Case Study

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Discussion

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