

United States Medical Device Reimbursement Basics



Beth Roberts
Partner
Hogan and Hartson
(202) 637-8626
BLRoberts@hhlaw.com

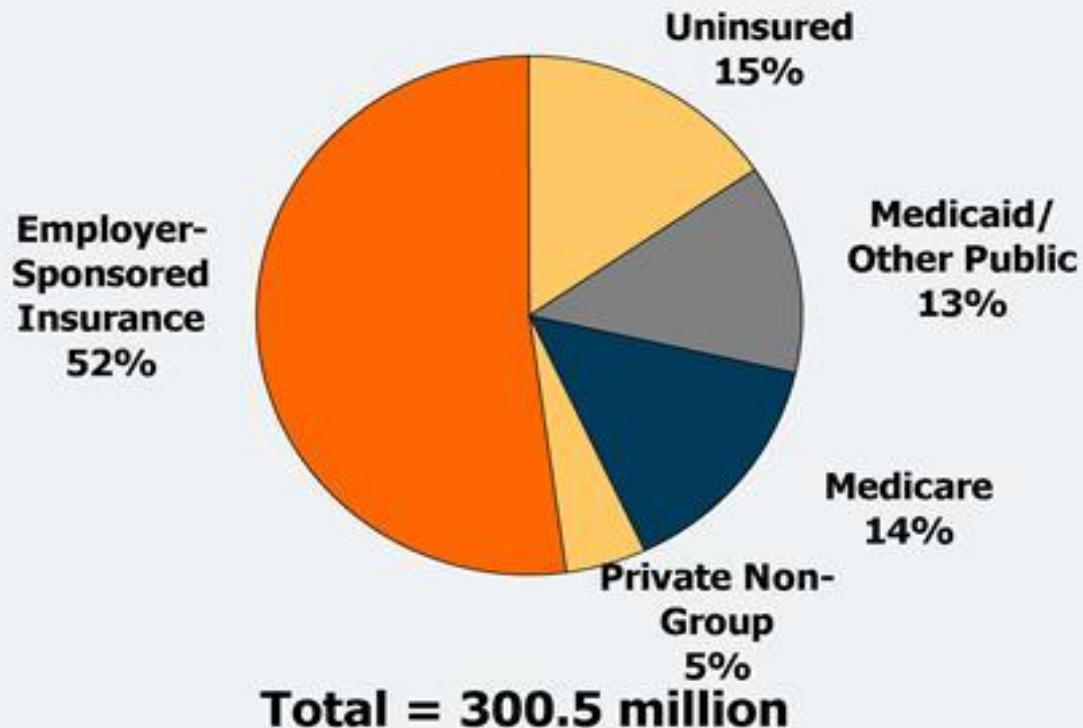
October 28, 2009

Agenda

- US Health Care Market
- Why Medicare Is Critical for Most Devices
- Three Components of Reimbursement
 - Coding
 - Coverage
 - Payment
- Health Insurance Reform in the US

US Health Care Market

Health Insurance Coverage in the U.S., 2008



NOTE: Includes those over age 65. Medicaid/Other Public includes Medicaid, SCHIP, other state programs, and military-related coverage. Those enrolled in both Medicare and Medicaid (1.9% of total population) are shown as Medicare beneficiaries.

SOURCE: Kaiser Commission on Medicaid and the Uninsured/Urban Institute analysis of March 2009 CPS



Private Payers

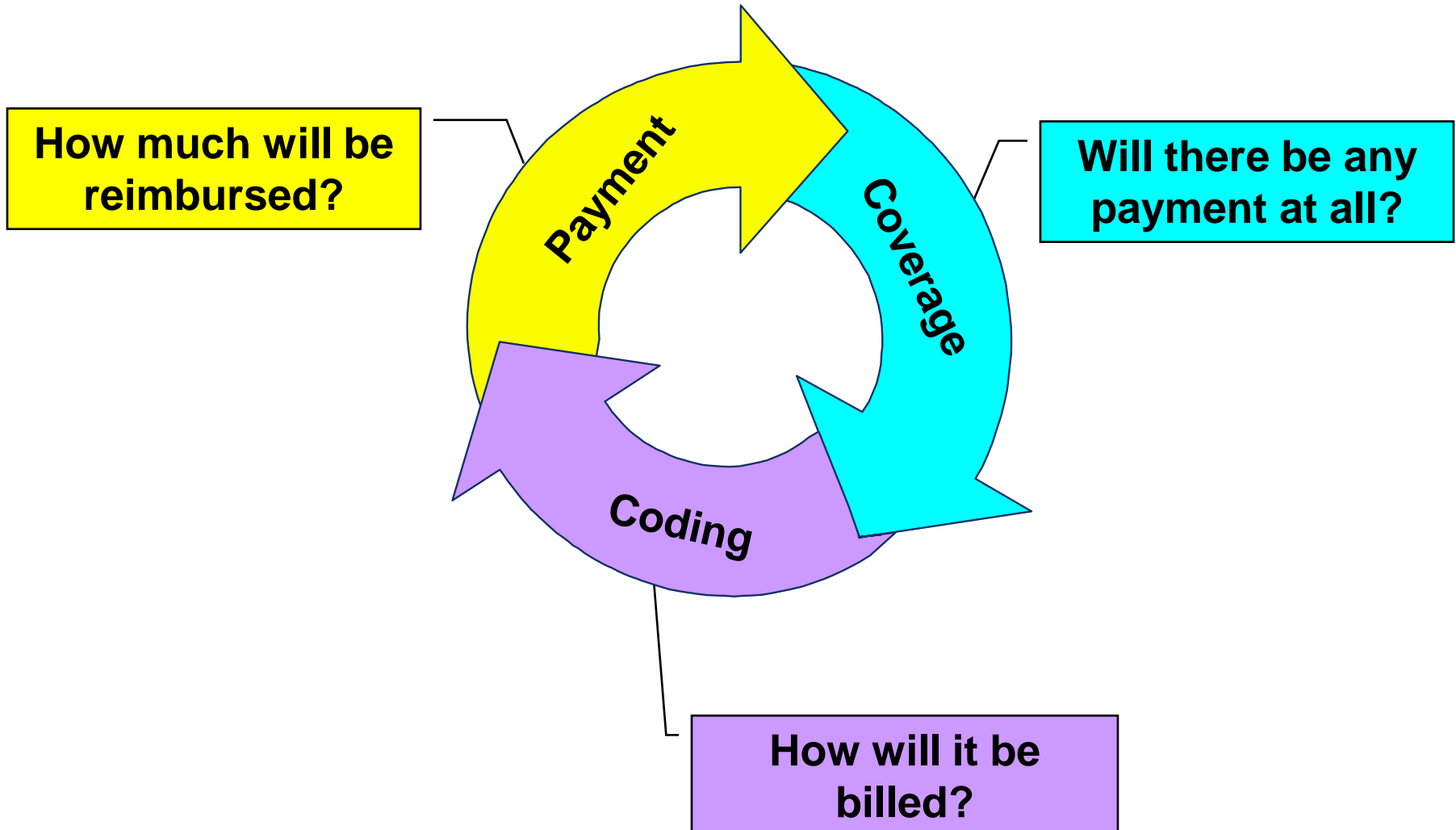
- Most Americans with private insurance receive coverage through their employers
- Cover approximately 250 million Americans, 67.9% of the U.S. population, according to the U.S. Census Bureau
- Over 1000 private health insurance companies
- Covered benefits vary, but many follow Medicare's lead for coverage and reimbursement

- A federal program established in 1965 to provide health insurance coverage to the *aged, disabled*, and those with *end-stage renal disease*
- According to Kaiser Family Foundation, Medicare covers approximately 44.2 million Americans as of January 2008.

Why Medicare Is Critical for Most Devices

- Most devices are used to treat diseases more prevalent in the elderly or for those who are disabled or with end-stage renal disease
- Private insurer policies vary dramatically
 - Payment rates are proprietary, but often are based on Medicare amounts
 - Some covered benefits and other requirements mandated by states
 - Very resource intensive to collect information, both by plan and by state
- Private payers often follow Medicare coverage policies
- When conducting a reimbursement analysis of the US market, Medicare provides a helpful baseline
- Some exceptions to the rule
 - Pediatrics
 - Cosmetic

Three Independent Issues



Coding

- Standardized coding systems are used so health care practitioners can reflect the items and services they provide on the claim form
- Accurate coding is crucial for processing claims and getting paid
- Existence of a code is not a guarantee of payment
- False Claims Act implications for recommending use of the wrong code
- Increasingly investors are asking about coding

Primary Types of Codes

- Healthcare Common Procedure Coding System (HCPCS) codes
 - Current Procedural Terminology (CPT) codes - Level I
 - Used to describe physician procedures
 - Owned by the American Medical Association (AMA)
 - Very long and political process
 - November deadline
 - Alpha-numeric codes – Level II
 - Established by the Centers for Medicare and Medicaid Services (CMS)
 - Used for durable medical equipment, prosthetics, and orthotics
 - Must be FDA approved with 3 months of marketing data
 - Early January deadline

Primary Types of Codes

- International Classification of Disease, 9th Revision, Clinical Modification (ICD-9) codes
 - Two types:
 - Diagnoses – Used on all claims
 - Procedures – Used on hospital inpatient claims
 - Maintained by ICD-9 Coordination and Maintenance Committee that meets twice a year

Coding - Key Issues

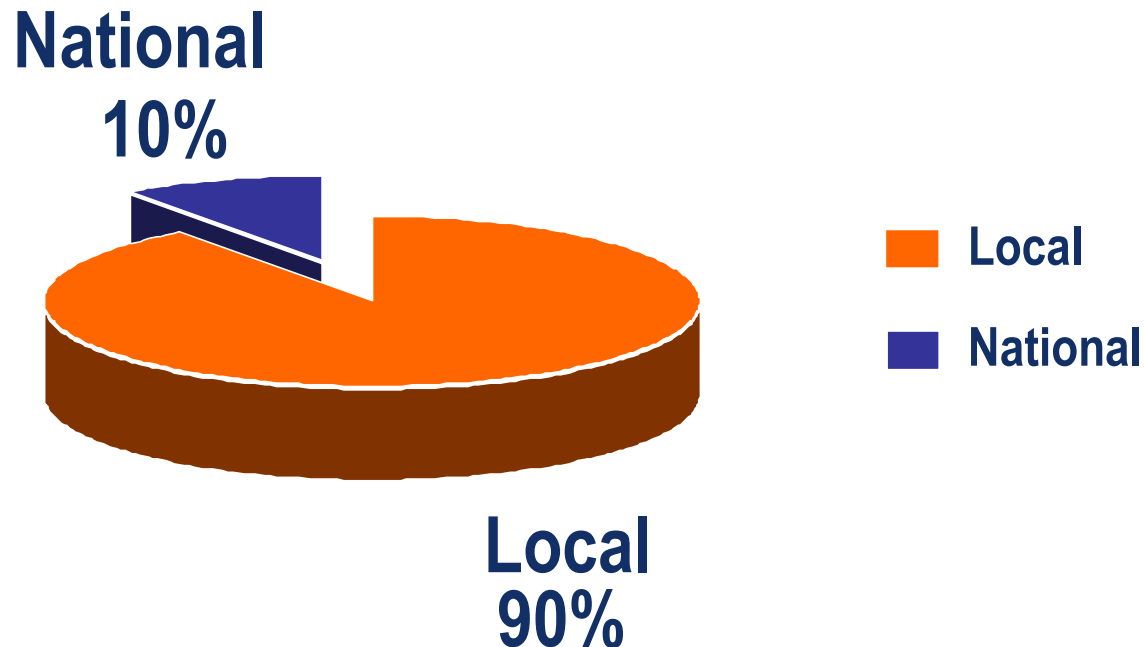
- Although codes do not mean coverage, unique codes are critical for technology uptake
- Miscellaneous codes allow billing upon launch; however, physicians often are frustrated by them as they require manual submission
- Deadlines are crucial when filing for new codes, particularly because of the long timeline
- Using an existing code is faster but will have significant reimbursement implications
- If CPT code is necessary, start the political process early
 - Work closely with specialty societies
 - Need widespread use
 - Must have US peer reviewed journal articles

To Obtain Medicare Coverage

- Must fall within a Medicare benefit category
 - Most devices covered as part of an inpatient or outpatient hospital procedure
 - Other devices covered as durable medical equipment (DME), prosthetics, or orthotics
- Must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”
 - Preference is for peer-reviewed medical literature showing benefit
 - Need to think about clinical literature early
 - Important to include Medicare beneficiaries in studies
- Must not be excluded by the statute (e.g., eyeglasses)

Who Decides?

- National Coverage Decisions (NCDs) – 18-24 per year for all services; Traditionally rare for drugs, but now more common
- Local Contractors – Decisions made through local coverage decisions (LCDs) or daily claims adjudication



Coverage - Key Issues

- Coverage is critical for a product's success
- Monitor LCDs and NCDs
- Crucial to have strong clinical evidence that includes Medicare beneficiaries; best to build into initial trials
- Cost currently is not a factor in making coverage decisions
 - Comes through the back door, however
- Stimulus package enacted earlier this year includes \$1.1 billion for comparative effectiveness research
 - Not clear whether and how this will be used to make future coverage determinations

Payment - Varies By Setting

- Physician office – Medicare Physician Fee Schedule
- Hospital inpatient - prospective payment system (IPPS) based on one Medicare Severity Diagnosis-Related Group (MS-DRG) payment
- Hospital outpatient – prospective payment system (OPPS) based on one or more than one Ambulatory Payment Classification (APC) payment
- Ambulatory Surgical Center (ASC) – Phase-in of ASC Payment System based on APCs at 65% of hospital outpatient rate
- DME, orthotics, and prosthetics – fee schedule
- Other payment systems for home health, skilled nursing facilities, or beneficiaries with end-stage renal disease

Payment for Physician Services

- Made under the Medicare Physician Fee Schedule
- Payment rates generally are calculated by adding the following three relative “weights” and multiplying the sum by a conversion factor:
 - (1) physician work
 - (2) practice expenses
 - (3) malpractice expenses
- The AMA collects data from its members and other specialty societies to establish the values for each of the above inputs; CMS accepts or rejects
- If physician purchases the device or disposable, its cost is reflected in the practice expense
- Flaw in conversion factor update mechanism causes substantial cuts each year unless Congress acts; -21.5% for 2010

Prospective Payment Systems

- Annual payment updates typically based on claims data
- Reimbursement strategy changes based on size of the bundle
- Catch is that new devices must have usage to be captured in data, but providers won't use them unless there's reimbursement
- New technology add-on payment mechanisms were created technologies in IPPS and OPPS
 - Clearly defined and limited criteria
 - Generally need clinical data to show that the technology is new and a substantial clinical improvement
 - Must meet cost threshold
 - Lasts 2-3 years until sufficient data is collected

Payment – Key Issues

- Device payment typically is included in underlying procedure
- Critical to assess payment rates in different settings; may change marketing strategy dramatically
- Think about physician work and practice expense during product design
- Take advantage of new technology mechanisms when possible
 - build collection of necessary clinical evidence into trials
 - assess potential eligibility before pricing product
- Payment systems are updated annually through the rulemaking process and legislative changes also are frequent; close monitoring of changes is critical
- Trends are to increase bundling and to cap rates in one setting at amounts from another setting

Health Insurance Reform

- Health care expenditures are projected to be about 17% of the gross domestic product (GDP) in 2009, increasing to nearly 20% by 2017
- Stark contrast between spending and quality of care delivered. Across 37 indicators, the US achieves a score of 65 out of 100 on 2008 Commonwealth Fund Commission National Scorecard:
 - 75 million adults (42%) uninsured or underinsured
 - U.S. ranks last of 19 countries on mortality amenable to medical care
 - U.S. health insurance administrative costs are 30-70% higher than in countries with mixed private/public insurance systems
- Deficits are growing—Federal and state governments will remain under significant pressure to reduce health care costs
- Health reform a high priority for Obama Administration and new Democratic Congress

Health Insurance Reform

- Not currently one reform proposal, but five – must be merged before enactment
- Would increase insurance rates by:
 - Creating health insurance exchanges
 - Making insurance more affordable through subsidies
 - Mandating coverage beginning in 2013
- Lots of controversy about a public option
 - Public option, if enacted, would at most only be a public plan that competes with private plans in the exchange
 - Senate Finance Committee bill would have these public plans be run by states
- Very little reform to the fundamental structure of health delivery or to contain costs over the long-term
- Continued questions about pay-fors

Key Reform Issues for Device Companies

- All bills would, at least temporarily, ensure Medicare physician payments are not cut
- The number of uninsured would decrease, and plans would be mandated to cover minimum benefit package, including inpatient, outpatient, and physician services
- Would enact several programs to experiment with improving coordination of care while realizing savings, including gainsharing, medical home, and chronic care management.
- Would expand comparative effectiveness research
- Would enact Physician Payment Sunshine
- Senate Finance Committee bill would impose an annual fee on device manufacturers/importers
 - Fees also would be applied to health insurers and branded drug manufacturers/importers

Annual Fee on Device Manufacturers/Importers

- Would be effective 2010 based on 2009 sales
- Total fee across all manufacturers to be \$4 billion
 - Fees are not tax deductible
- Applies to any medical device intended for humans
 - Excludes sales attributable to Class I products and sales of Class II products sold at retail for up to \$100/unit
- Based on market share as determined by Treasury Secretary
 - Manufacturer/Importer to file annual report for prior calendar year
- Market Share Calculation
 - Manufacturer total domestic sales divided by all manufacturer domestic sales
 - Domestic sales to be discounted/weighted to benefit smaller manufacturers

For more information on
Hogan & Hartson, please visit us at

www.hhlaw.com

Abu Dhabi
Baltimore
Beijing
Berlin
Boulder
Brussels
Caracas
Colorado Springs
Denver
Geneva
Hong Kong
Houston
London
Los Angeles
Miami
Moscow
Munich
New York
Northern Virginia
Paris
Philadelphia
Shanghai
Tokyo
Warsaw
Washington, DC