Getting Your Product Covered and Paid for in the U.S. Market:

A Skeptical Payer's Perspective

11 May 2009

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MarketReach America

Today's Healthcare Environment Costs Continue to Rise

- More treatments available
- Technology advances
- Increase of proactive diagnosis of conditions
- Preventative care
- Aging population
- Increased chronic illness in a younger age
- Direct-to-consumer advertisements

Annual Health Care Spending
•1970-$75 Billion
•2005-$2.0 Trillion
•2015- $4.0 Trillion

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Who are the Payers?

Health Plans	Employer based Payers	Governmental Payers
Aetna	Employer Coalitions	Medicare
Wellpoint	Hart Taftly/Unions	Medicaid
United Healthcare	Individual Employers	SCHPS
Blue Cross/Blue Shield	Third Party Administrators	Veteran's Admin./DOD

Should the Patient be considered a viable "payer" ?

Examples of payer types

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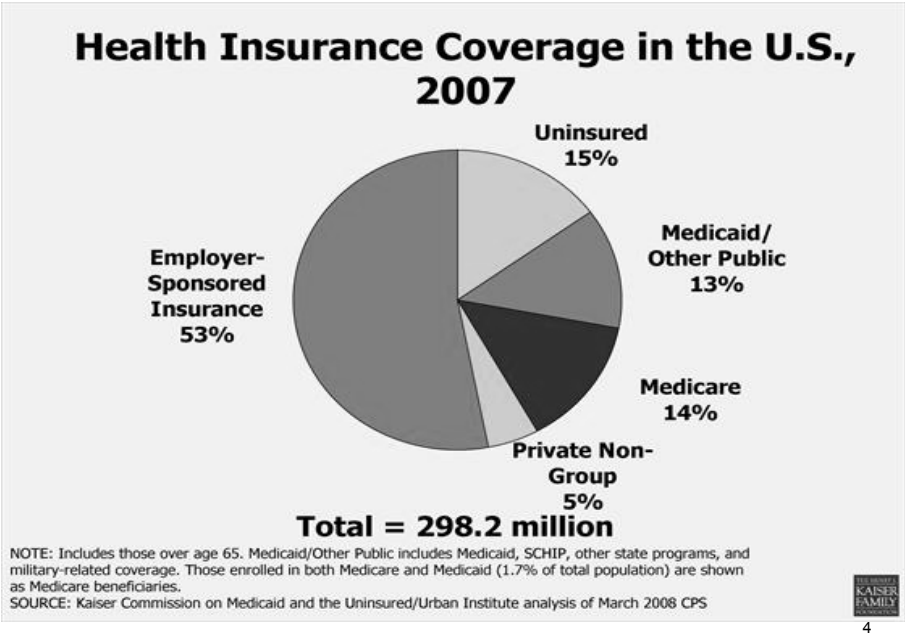

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Employers Build Value in Increments

change is driven by accessible data

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The Hidden Voices at the Decision Table

- Benefit Consultant (Hewitt, Mercer, Watson Wyatt)
- Independent Technology Assessment Companies (Milliman, ECRI, Hayes)
- Advocacy Groups (American Diabetes Association, American Heart Association)
- Provider Specialty Societies (American College of Cardiology, American Academy of Pediatrics)

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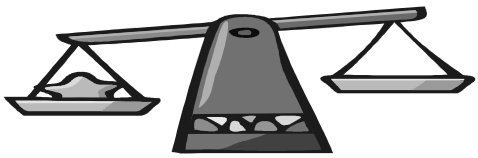
Physician Influence on Payers



Physicians affinities with device firms

Physician affinities with the payer

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It is important to define your product in order to best create a coverage road map

Where is the Product Covered	Who Will Utilize your Product	Where will the Product be Used
Medical benefit	Patient/caretaker	Inpatient
Pharmacy benefit	Physician	Outpatient
Durable Medical Equipment	Ancillary health care worker	Home Health
Special Rider		Home

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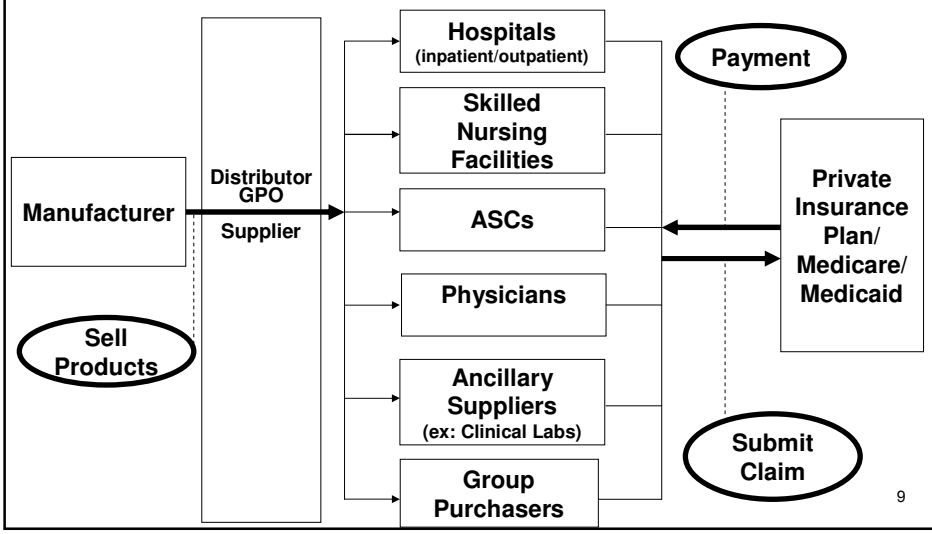
How Does A New Medical Device or Drug Fit Into The U.S. Health Care System?



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Success is like running the hurdles

- FDA
- Payers
- Providers
- Patients

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Where do coverage requests come from

- Product manufacturers
- Patients
- Physicians
- Pt advocacy organizations or patient advocates

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Coverage 101

- Not all treatments fall under the scrutiny of the FDA
- FDA approval does not necessarily assure level of efficacy that other payers require
- Health plans do technology assessment in order to best assure that patients receive safe and effective treatments
- Payers look at issues such as new technology that provide improved efficacy, decreased cost or less invasive

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Placement of Medical Device in Healthcare Spectrum

- New Technology
- Replacement Technology
- Additive Technology

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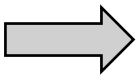
Process for Evaluation of New Product, Service or Technology

Formal

Reproducible

Evidence Based



Pharmacy & Therapeutics Committee

Technology Assessment Committee

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Decision Process of Payers

Clinical Issues

- Safety
- Efficacy
- Outcomes
- Appropriate for plan's patients
- Impact on current treatment option
- Analysis by technology assessment groups

Non-Clinical Issues

- 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

- 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

- 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

- 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

Payer

- Head to head design
- Large diverse populations
- Diverse settings
- Long term follow up
- Considers natural history of the disease

Industry

- Feasibility of the trials
- Costs to the trials
- Scalability of trials
- Time to market

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The Outcome Endpoint Controversy

Surrogate Endpoints

Example:
Narrowing of arteries

True Endpoints

Example:
Cardiac event

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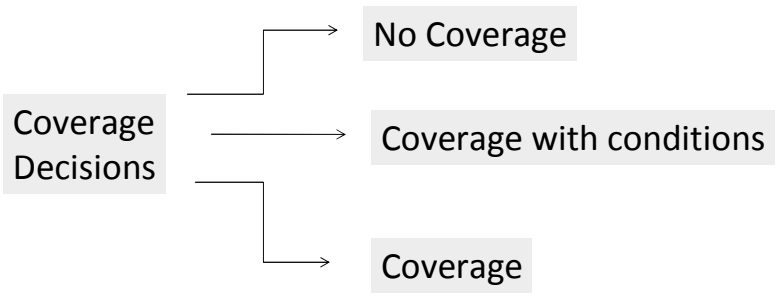
Coverage Decision Tree



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

"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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Device Manufacturer Opportunity: Focus on Data Expansion

- Registries
- Broaden outcomes to look at performance data on the entire course of treatment
- Look at costs beyond direct medical costs

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Beyond Coverage: Where's the Dollar

- Creation of a procedure code
- Price lists (Often difference for inpatient verses outpatient)
- Pricing often associated with how the device may reduce total costs or enhance care

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How is Reimbursement Determined

- Reimbursement "pegged" to CMS reimbursement of the product
- Bundled payments (hospital product)
- Reimbursement equality with other similar products
- Cost implications and off-sets

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How are costs evaluated

- Cost of the product
- Cost of the expanding ability of product
- Impact on the use of subsequent health care
  - Risks
  - benefits
- Benefits associated with the imaging
- Is the imaging replacing or augmenting other care
- Risk associated with treatment or testing that it is replacing

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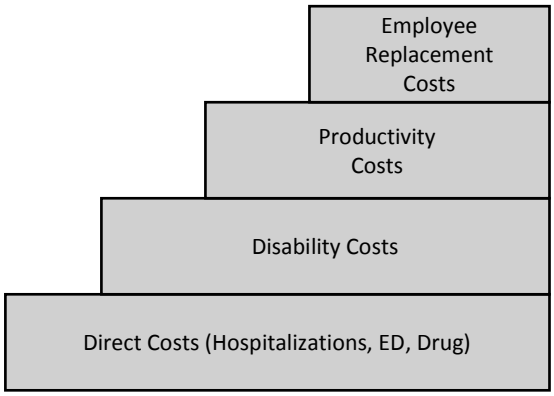
Types of Costs Evaluated



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Newer Issues to Consider

- Center for Comparative Effectiveness
  - Registries, cooperative studies, head to head trials
- Emerging Payer Plan Designs
  - Consumer Driven Health Plans
  - Value Based Plan Design
- Pharmaco-economics
- Reference Pricing
- Disease/Health Management
- Manufacturer focused Performance Guarantees
- Financial Incentives
  - Physicians
  - Patients
- Humanitarian Coverage

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Definition
Comparative Effectiveness

Research evaluating and comparing the implications and outcomes of two or more health care strategies to address a particular medical condition

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Comparative Effectiveness

- "Must haves" versus "nice to haves"
- Interventional versus database studies
- Met-Analysis versus Head to Head Trials
- Clinical versus Cost
- Government sponsored versus Private Sponsorship

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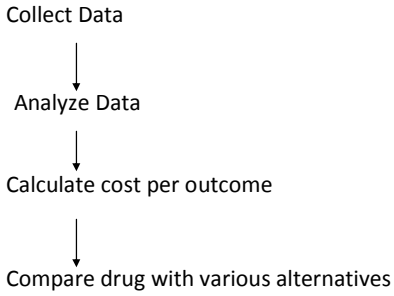
Pharmaco-economics shaping Policy and Programs

Pharmaco-economics identifies, measures and compares costs and consequences



Numerator=costs
Denominator=clinical, economic or humanistic outcomes

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If cost is included in the Comparative Effectiveness Equation Information Required by a Payer:

- Current standard of care associated costs
- New product associated costs
- Improvement of health outcomes associated costs
- Speed of diagnosis
- Consistency of results

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Example: CT for Abdominal Aortic Aneurysm

- Role of ultrasound
- Use of angiogram or aortogram
- Emerging technologies such as CT angiography

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Evaluation of the Use of CTA

Utilization

- Utilization increased for CTA between 2001 and 2005
- Overall testing increased

Outcomes

- Utilization can offset complications. But did it?
- Missed diagnosis could be made. Was this the case?

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Coverage Decisions

- Medicare- less flexible, legally dictated, at times politically motivated
- Private Payer-greater flexibility, some state influence

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Initial Focus of Product Manufacturers at Launch

- Coverage focus
  - Medicare versus private payers
  - Third party payer versus individual payer
- Attributes of the product will help to set a course (i.e., “Life style” product, patient attributes of the product)

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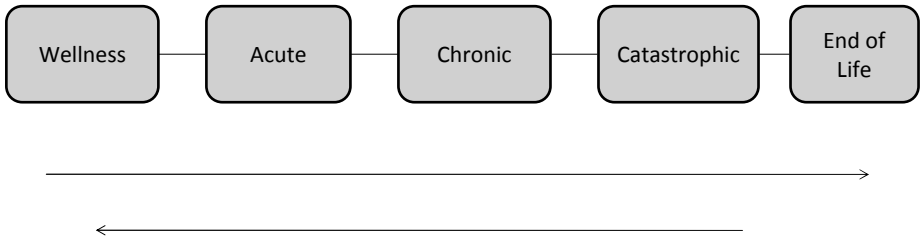
The Healthcare Lifecycle



Healthcare is Fluid

All Sectors are seeing an increase in Utilization and costs

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The US Healthcare Environment 2009
Desperate times take desperate measures

- Utilization management-1980s
- Disease Management-1990s
- Wellness-2000
- Consumerism-2000

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Employer Payers Utilizing Disease Management Strategies

EMPLOYERS Disease Management Programs	Currently Supported
Diabetes (pediatric & adult; types 1 & 2)	82%
Asthma	68%
Coronary artery disease (CAD)	68%
Heart failure	59%
Chronic obstructive pulmonary disease (COPD)	55%
Hypertension	55%
Depression/mental health	50%
Low back pain (chronic)	45%
High-risk maternity	32%
Oncology	27%
Musculoskeletal – arthritis, hip replacement, knee replacement or osteoporosis	23%
Osteoporosis	23%
Arthritis	18%
Atrial fibrillation	18%
Kidney disease management	18%
Low back pain (acute)	18%
Fibromyalgia	14%
Inflammatory bowel disease (IBD)	14%
Irritable bowel syndrome (IBS)	9%
Urinary incontinence	9%
Headache	5%
HIV/AIDS	5%

DMAA 2008

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Example:
Home Monitoring Associated with Disease Management
The Case of Home INR testing

- Home prothombin time testing systems are portable coagulation monitoring devices intended to be used at home (Pro Time, AvoSure PT System, Harmony INR Monitoring System)
- Measures PT and calculates INR
- Requires frequent interaction between the patient and the healthcare team
- Medicare initial coverage 2002
- BCBS coverage 2006
- UnitedHealth coverage 2008
- Medicare expanded coverage by diagnosis 2008
- Has been shown to:
  - Increase quality
  - Increase clinical outcome
  - Decrease costs

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Value Based Plan Design for Self Funded Employers and Third Party Payers

- Patient cost share continues to increase
- Patient behavior associated with cost may be increasing healthcare costs to society as a whole
- In VBPD,coverage is based on value, not cost
- Who decides the definition of value and to whom is the value attributed?

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Example: External Ambulatory Insulin Infusion Pump

- Examples include OmniPod Insulin Management system, Paradigm Real time Insulin pump, Continuous Glucose Monitoring System
- Diabetes outcomes improve with tight control
- Insulin pumps have been shown to improve outcomes with a specified sub population

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Coverage of Insulin Pumps

- Medicare
  - Covered on a rental basis (capped rental)
  - CMS requires quarterly visits with healthcare provider
- Health plans
  - Covered on a purchase basis
  - Required visits with a healthcare provider vary from quarterly to semi annually
- Value Based Insurance Plans

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Example: Aetna Coverage Rationale of Diabetes Products

- Won't cover products that are:
  - Experimental and investigational (A1C Now Diabetes Monitor home testing monitor)
  - Patient preference (Advanta Jet, insulin jet injector)
  - Lack of data to substantiate efficacy (TheraSense Free Style Tracker for blood glucose monitoring)
  - Lack of data to substantiate safety (Biostator Artificial Pancreas)

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Humanitarian Device Coverage

- Safe Medical Devices Act of 1990 with final rule in 1996
- Humanitarian device is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4000 individuals in the US annually
- Humanitarian device application is similar to pre market approval but is exempt from the effectiveness requirements
- Product does not pose an unreasonable or significant risk of illness or injury
- No comparable devices are available to reat or diagnose the disease or condition
- Post marketing studies are often required

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Example: Levitronix Centrimag Right Ventricular Assist System

- Indicated for temporary circulatory support for patients in cardiogenic shock due to right ventricular failure
- Indicated to stabilize hemodynamic condition of the patient that have not responded to other therapies

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Creative Contracting Concepts

- Transition from service guarantees to insurance risk-
  - Medicare risk corridors
  - Generic or class financial risk
- Guarantees on product outcomes-

  Refund given to payer if product fails to meet agreed performance targets when appropriately utilized
  - Example in US- Geisinger Health Plans-Heart by-pass surgery
  - Example in UK-Velcade

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Direct to Consumer Advertising

Good for patients and Manufacturers

Bad for Payers

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The Patient as a Payer
Example: Minimally Invasive Knee Replacement

- Knee replacement is one of the most common surgeries in the Medicare population
- 2003-first 50 patient study comparing process and outcomes of minimally invasive surgery to traditional
  - Similar surgical times
  - Inpatient no greater than 23 hours
  - Rehabilitation shorter
  - Revision rates at this time <10%

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Minimally Invasive Knee Replacement Coverage

- Medicare still does not cover this procedure as it remains under the category of "experimental"
- Blue Cross Blue Shield began covering in 2007 for a subset of patients
- Largest portion of patients remain self pay

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Summary
What Manufacturers Need to Do

- Know who the coverage decision maker(s) are
- Who is at risk for the cost
- Who will benefit from your product
- Seek input from payers to understand what information they will require
- Understand the patient demographics that your product is focused on
- Understand coverage of similar products

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MarketReach America

The End

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