

# Industry and Payers

- **Evidence-Based Medicine and Technology Assessment**
- **Coverage with Evidence**
- **Pay for Performance**
- **Gainsharing**

# Industry and Payers

- Increasingly, payers, are using clinical evidence to support coverage decisions, which, in turn, may further shape manufacturers' development of clinical evidence
- Industry often feels payers are doing so in order to slow technology dissemination and reduce costs rather than to improve outcomes

# Why Isn't Regulatory Approval Enough?

## Regulator

## Payers/Provider

- **Safety**
- **Efficacy**
  - **Benefit of using a technology for a particular health problem in ideal conditions**
- **Substantial equivalence or comparison to placebo**
- **Intermediate, short-term outcomes**

- **Everything in the left column plus**
- **Effectiveness**
  - **Benefit of using a technology for a particular health problem in general or routine conditions**
- **Comparisons to standard of care and experience relevant to members**
- **Long-term health outcomes**
- **Operational impact**

# Process:

## Blue Cross Blue Shield TEC

- The technology must have final approval from the appropriate government regulatory bodies.
- The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
- The technology must improve the net health outcome.
- The technology must be as beneficial as any established alternatives.
- The improvement must be attainable outside the investigational setting.

# Use of Intermittent or Continuous Interstitial Fluid Glucose Monitoring in Patients with Diabetes Mellitus

- **The technology must have final approval from the appropriate governmental regulatory bodies.**
  - The Continuous Glucose Monitoring System (CGMS®) (Medtronic MiniMed, Northridge, CA) received FDA PMA approval (P980022) on June 15, 1999.
- **The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.**
  - ... however, the largest study did not demonstrate any incremental effect on HbA1c.
  - ...observed changes over time in group HbA1c levels were small (<0.5%)
  - ...No significant improvements in quality of life were demonstrated.
  - ... the clinical significance of this effect alone is not well established. No studies evaluated the more important question of whether these devices could significantly reduce the frequency and severity of clinically significant episodes of hypo- or hyperglycemia with associated morbidity.
  - Thus, no conclusions can be drawn regarding the effects of interstitial fluid glucose monitoring on health outcomes.

# CGM continued

- **The technology must improve the net health outcome; and**
- **The technology must be as beneficial as any established alternatives.**
  - There is insufficient evidence to permit conclusions on the effect of using interstitial fluid glucose monitors on health outcomes.

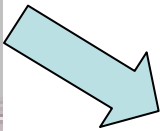
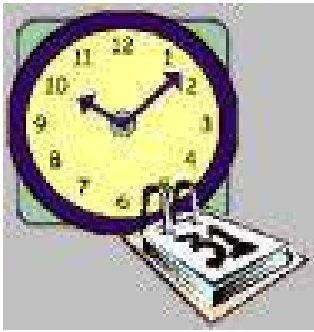
# CGM continued

- **The improvement must be attainable outside the investigational settings.**
  - Whether the use of interstitial fluid glucose monitoring improves health outcomes in patients with diabetes mellitus has not been demonstrated in the investigational setting.

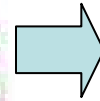
**Therefore, based on the above, use of interstitial fluid glucose monitoring in patients with diabetes mellitus does not meet the TEC criteria.**

# How Can One Body of Evidence Yield Different Conclusions?

Timing



Evidence

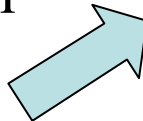


Analytical  
Methods



**"The  
Answer"**

Problem  
Formulation



Clinical  
Expertise

# What we do versus what we *should* do

- Choose the shortest path to regulatory approval
- Clinical trial designed to prove product is safe
- After we launch the product, we can worry about reimbursement
- There must be something wrong with you if you can't "get us reimbursement!"

# Predicted Clinical Restenosis Rates

## Diabetes

Adapted from Ho KKL et al. AAC 1998

Vessel Diameter	10 mm	15 mm	20 mm	25 mm	30 mm
2.5 mm	23%	26%	29%	31%	34%
3.0 mm	15%	17%	20%	22%	24%
3.5 mm	10%	11%	13%	15%	16%
4.0 mm	6%	7%	8%	9%	10%

## No diabetes

2.5 mm	18%	20%	22%	25%	27%
3.0 mm	11%	13%	15%	17%	18%
3.5 mm	7%	8%	9%	11%	12%
4.0 mm	4%	5%	5%	7%	7%

# CMS' Coverage With Evidence (CED) Policies are Intended to Redefine Evidence Needed for Coverage

- CMS is **using its authority as a payer** to drive additional data generation to inform its coverage and payment decisions through its “coverage with evidence development” (CED) policy
- CED requires the **collection of data (e.g., registries and clinical trials) as a condition of Medicare national coverage**
- Draft guidance released by CMS in April 2005: **CED will be applied in limited circumstances, including:**
  - When CMS has **concerns regarding a technologies' off-label uses, side effects, safety and efficacy** in the Medicare population, appropriate **patient selection criteria, and comparative effectiveness**
- CMS plans to release a revised guidance document in early 2006

# What Is Pay-for-Performance?

- Establishes processes to develop, refine and update quality measures
- Initially, pay providers (hospitals and physicians) to report the measures, then move to paying relative to performance (e.g. bonuses for top percentiles, penalties for bottom)
- Commitment to link future increases in Medicare physician payment to P4P
- Without a formula fix, physicians face average cuts of 5% per year over the next seven years
- Hospitals already report quality measures (Hospital Compare) or suffer .4% reduction in MBI (moves to 2% reduction for FY07)

# P4P: Criteria for Measures

- Evidence-based
- Accepted by quality experts
- Derived from currently collected data when possible; low burden of collection and analysis
- Risk-adjusted if outcome measure
- Applicable to a broad range of providers and physicians
- Within the control of the provider or physician
- Relevant to an area in need of improvement

# P4P: Industry Policy Position

- Keep it about quality and ensuring appropriate use – not economic benchmarking
- Ensure frequent updates for new process measures/new technologies (no new coverage process)
- Specialty societies should play a critical role
- Encourage remote monitoring – don't forget about payment for the underlying service

# P4P: Implications for Industry

- Understand current quality measures that relate to your business
- Develop evidence to support adoption of new measures
- Stay close to specialty societies/guideline process
- Determine opportunities to create/influence measures to encourage adoption of our therapies

# Hospital Compare Measures: Heart Attack

Aspirin at Arrival

Aspirin at Discharge

ACE Inhibitor for LVSD

Beta Blocker at Discharge

Beta Blocker at Arrival

Adult Smoking Cessation  
Advice/Counseling

Thrombolytic Agent Received Within  
30 Minutes Of Arrival

PTCA Received Within 90 Minutes Of  
Arrival

# Hospital Compare Measures

## **HEART FAILURE**

Assessment of Left Ventricular  
Function

ACE Inhibitor for LVSD

Discharge Instructions

Adult Smoking Cessation  
Advice/Counseling

## **PNEUMONIA**

Oxygenation Assessment

Pneumococcal Vaccination

Initial Antibiotic Timing

Blood Cultures Performed  
Before First Antibiotic  
Received

Adult Smoking Cessation  
Advice/Counseling

# What is “Gainsharing” ?

- **Aligning physician and hospital incentives by giving the physician a share of any hospital savings attributable to the physicians efforts**
  - Reduce the number of vendors/products offered in a Cath Lab to encourage aggressive pricing
  - Substitute clinically equivalent devices with less costly devices

# Gainsharing continued ...

- **Requires lengthy OIG approval, BUT Medicare is encouraging Demonstration Projects in 2007**
  - Financial incentives with a limited duration & amount
  - Specific cost saving identified
  - No adverse effect on patient care
  - Applies to all Payers
  - Base threshold set
  - No limit on product choice
  - Written patient disclosures
  - No inappropriate 'steering'
  - No shifting of cost savings
- **Non-Gainsharing Models – Hospital provides non-financial rewards to physicians**
  - New Cath Lab

# Can Industry and Payers Work Together?

- Meet early during clinical trial design
- Agree on metrics
- Agree to compromise
- Accept the business realities each must face
- What else?