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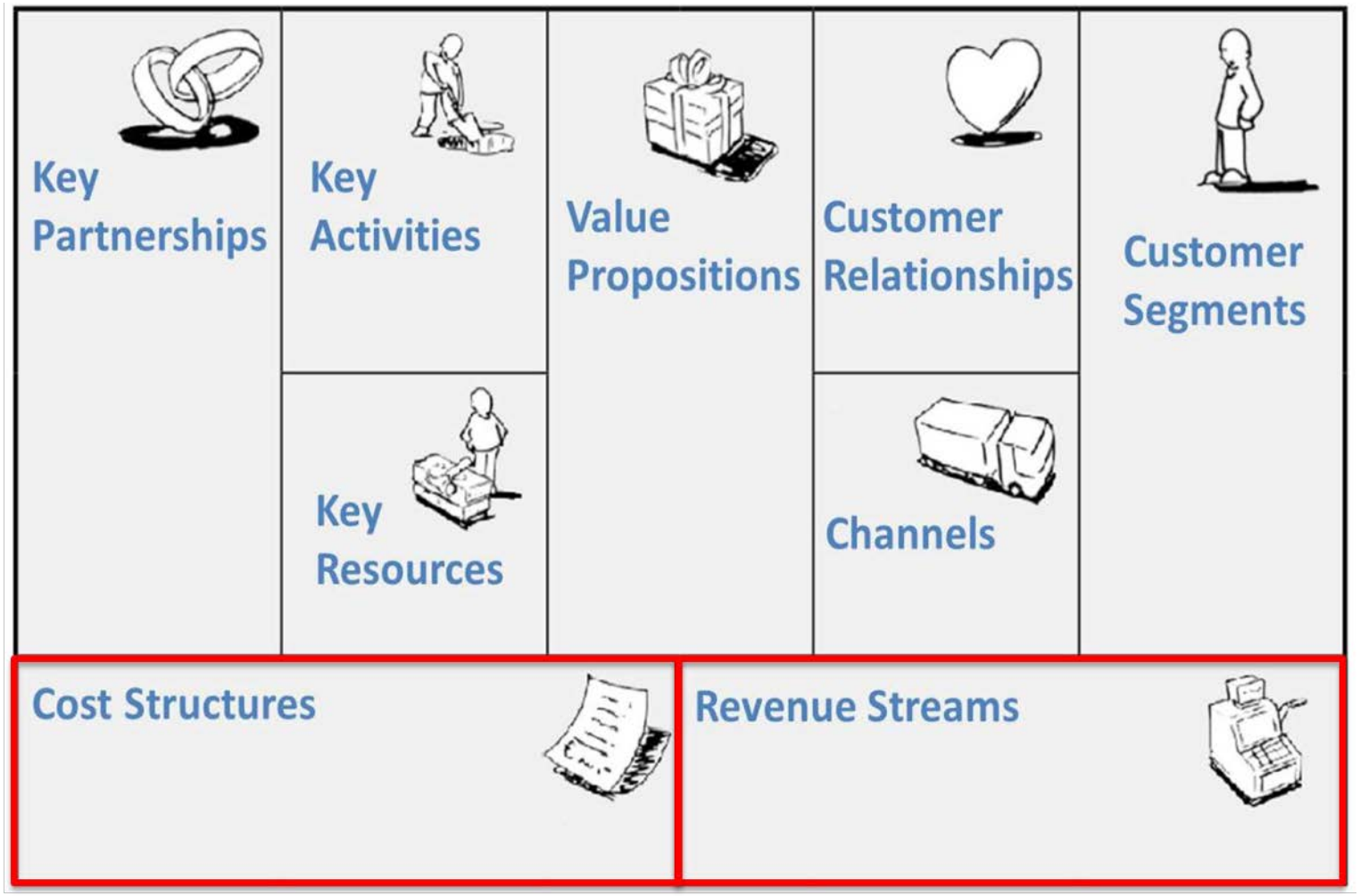
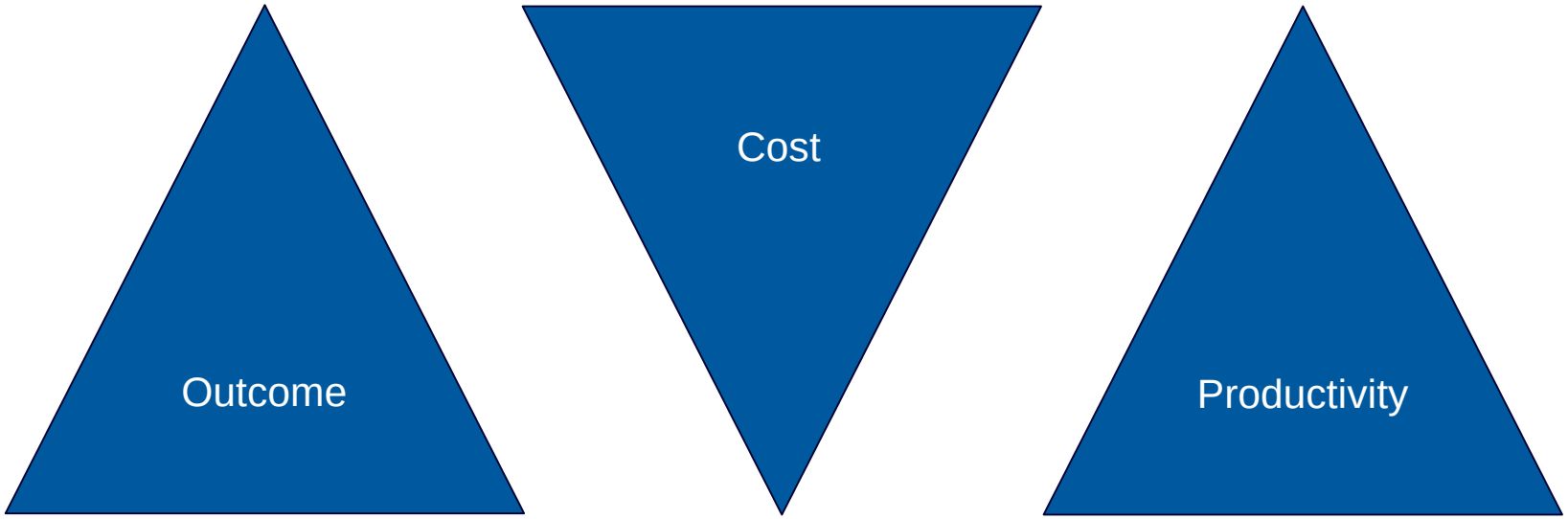
Cost, Reimbursement and Payers In Medtech Commercialization

Mark Low – June 21, 2017

Ecosystem - The Net of all the Influences that will Make or Break your Business



Healthcare Ecosystem Focuses on Economic Value Driven by Outcome, Cost and Productivity



The Cost Value Driver is Lowering the Total Relative Cost of One Approach Versus Alternatives

Product Cost Fundamentals

- Manufacturing Cost
  - Material, Labor, Overhead
- Distribution Cost
  - Direct/Indirect Selling Cost
  - Duties, Freight
- Cost of Installation
- Cost of Training
- Cost of Warranty

Plus:

- R&D
- Marketing

Cost of Use Fundamentals

- Use of Resources
  - People
  - Number of Products
  - Time

- Potential Incurred Expenses
  - Shelf Life Costs
  - Preparation for Use
    - Sterilization, cleaning
    - Pharmacy prep
  - Maintenance
  - Adverse Events
    - e.g., hospital acquired infections
  - Unreimbursed Costs
    - Difference between purchase cost and reimbursement rate
    - e.g., 30 day readmission for heart failure patient

Case Example:
Pricing a New Diagnostic Test

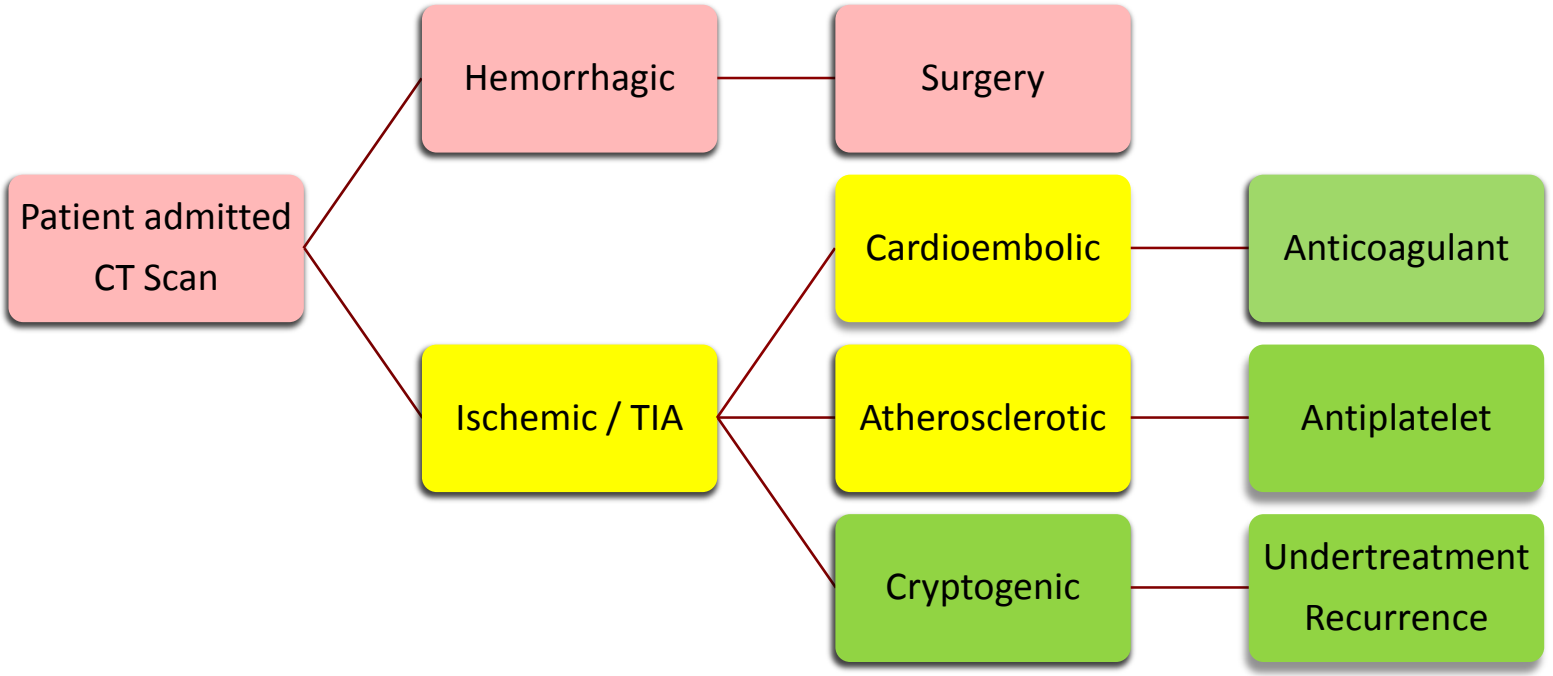
Situation:

- In about 30% of patients, the cause of ischemic stroke is indeterminate, causing uncertainty as to the best treatment pathway, and necessitating extra tests, increased physician time, extended hospital stay, potentially under-treatment leading to higher recurrence rates.

- A start-up company is developing a gene expression diagnostic test to help determine the cause of stroke.

- The value proposition is that it can solve the problem of guidance in stroke of unknown cause, and place patients on proper acute therapy to avoid stroke recurrence.

Diagnosis and Treatment of Ischemic Stroke



Level 1	**Level 2**	**Level 3**
20 min	0 – 4.5hr	5-10 days
ER	Neurologist	Admittance
Hemorrhage	tPA	Acute therapy

Time, Tests, and Costs

DRG 61 - 63 → Ischemic stroke reimbursement → $8,000 to $16,000

Emergency Triage

- Imaging (CT, TEE, MRI, carotid)
- Blood Work
- Spend ≈ $2K

Neurologist Workup 0-5 hours

- Clinical Evaluation (History, risk)
- Spend ≈ $3K

Admission 5-10 days

- 24-48hr Monitoring
- Other Testing
- Spend ≈ $10K

Reimbursement and Pricing Analysis

- Test is potentially eligible for reimbursement under existing DRG codes.
- The test *may* offset need for certain additional in-hospital tests.
- Based on the estimated costs of diagnosis and care, there *may* be “margin” in the DRG to accommodate this incremental test at a charge of $1100.

Is this an appropriate way to assess pricing options?

Case Example 2.
Calculation of Procedure Cost Saved

Device to clean laparoscope lens intra-operatively
Surgical team remained consistent and the workflow was unchanged.
Overall surgical time from incision to closure was decreased from 101 to 91 minutes.

This represented a 10 minute time savings attributed directly to {Product Name}.

OR Cost / Minute	Time Savings	Cost / Case	Est. Annual Cases	Annual Savings
$62	10 Minutes	$620	240	$148,800

Is This Real Savings?

Examples of True Cost Savings

- Acute:
  - Reducing the number of diagnostic tests that need to be done
  - Reducing the number of devices or instruments that need to be used
  - Enabling another procedure to be done within the shift
  - Shortening length of hospital stay by a day or more
- Over Time
  - Eliminating adverse events that require follow-up treatment

Reimbursement

Reimbursement Fundamentals

Coverage – There is no reimbursement without coverage.

- First question: Is technology or service similar to existing billing code or payment system.
- Two paths to obtaining coverage decision – both take time
  - Local – determined by private insurers
  - National – determined by CMS

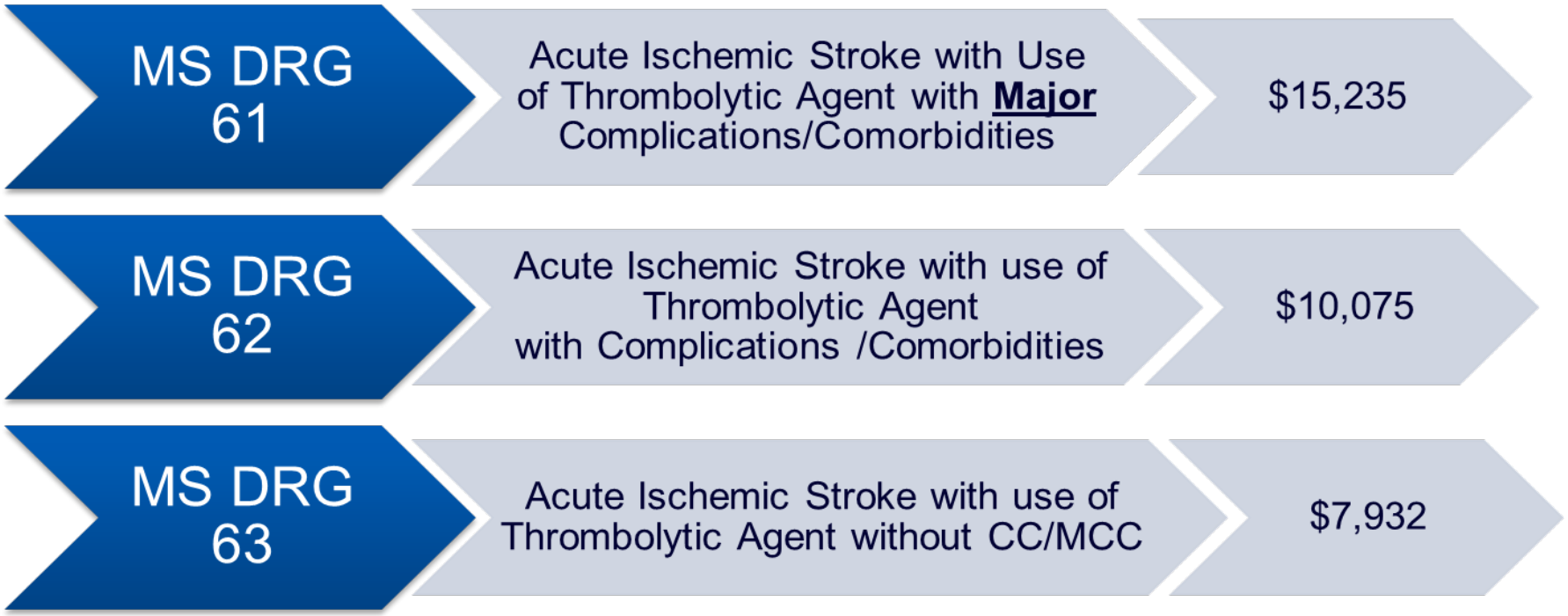
- Special Case: Therapeutics and Formularies
  - Insurers do not pay for prescriptions through coded billing.
  - Use formularies – lists of approved drugs for which they provide coverage
  - Medications chosen by independent Pharmacy and Therapeutics Committee
  - Typically formularies grouped by tiers with different associated co-pays, after meeting deductible requirements.

Reimbursement Fundamentals, cont.

Coding – Without a code there is no payment.

Acronym	Meaning	Explanation/ Comments
ICD-10	International Classification of Diseases – 10th revision	Example: 715.0 Osteoarthritis as DJD // 733.9 Osteoporosis as a co-morbidity
DRG	Diagnosis Related Group	This is how CMS (Medicare/Medicaid) pays for procedures. The DRG relative Weight x the Hospital Base Rate = Hospital Payment for the procedure. The payment covers ALL OR expenses, post-op, and even any complications that occurs
APC	Ambulatory Payment Categories	For Outpatient Care
CPT	Current Procedural Terminology	A 5-digit number that is used by the physician to describe service or procedure. This determines how much the physician is paid
RVU	Relative Value Unit –the multiplier that is used to calculate surgeon payment	Number split into 3 parts to reflect the providers' work/time/training required, malpractice expense, practice expense. Each CPT has RVU
GPCI	Geographic Practice Cost Index	Another multiplier that accounts for the economic variation per region
HCPCs	HealthCare Procedure Coding System	Covers other services, products, and supplies not found in CPT codes. Example: durable equipment

Diagnosis/Treatment Codes



Medicare Severity – Diagnosis Related Group

Reimbursement Fundamentals, cont.

Reimbursement Categories

- Inpatient Hospital Care (Prospective Payment)
  Based on classification of diagnostic related group (DRG)
- Outpatient Hospital Care
  Based on Ambulatory Payment Classification – (APC)
- Physician Services Payment – Based on CPT or HCPCS codes
- Laboratory Services (Clinical Laboratory Fees)
- Durable Medical Equipment, Prosthetics, Orthotics, Supplies
- New Technology Add-on Payments, New Technology APC,
  Pass Through Payment.

Payers and Payment Systems

Who Ultimately Pays for the Product Use?

- Federal Government – Medicare
- State Government – Medicaid
- Commercial Payers
  - Private Insurance – Blue Cross, Aetna, Kaiser, others
  - Company Benefit Plans
- Self Pay
- Philanthropy
- No one – financial loss to hospital or practice

Changing Environment: Medicare Payment Innovation

- Accelerating Change, Promoting Best Practices
- Provider Accountability and Risk Sharing
  - both for individual episodes of care and over time

- Hospital Value-Based Purchasing Program
- Hospital Readmissions Reduction Program
- Hospital Acquired Condition Penalty
- Merit Based Incentive Payment System
- Bundled Payments for Care Improvement Initiative
- Medicare Shared Savings Program - Accountable Care Organizations

Summary, Key Take-Aways

- One way or another, a product must lower the overall cost of diagnosis or treatment to the healthcare system.
- Payment to the healthcare system is primarily by reimbursement.
- Reimbursement is strictly controlled, and may be an insurmountable barrier to sales, utilization, and market penetration.
- You can’t start too early to understand your product costs and reimbursement strategy.

Guidance for Analyzing Cost and Reimbursement, Determining Pricing

- Learn what tests or procedures comprise the current standard of care.
- Track the coding and billing process at hospitals or sites where your product will be used. Follow the money.
- Determine how much the hospital or site actually gets paid.
- Talk to Supply Chain personnel, ask how products get approved for purchase.
- Ask how drugs get on formulary. What are the charges and co-pays.
- Look up coding and reimbursement guides for similar products from companies.
- Hire reimbursement consultant to profile procedure coding and reimbursement rates.

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