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Today's Presentation

Part I: US Health Policy

Part II: Reimbursement

- Fundamentals
  - Coding
  - Payment
  - Coverage
- Marketing to Payers

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REIMBURSEMENT STRATEGIES, LLC

Payer Relations for the LifeSciences

Reimbursement Strategy

Payer Relations

Health Economics

- Edward Black, Founder
  - 25+ Years within the Blue Cross Blue Shield Health Plan System
  - Advisor to the University of MN Office for Technology Commercialization
  - Member: Medical Industry Leadership Institute, LifeScience Alley, BioBusiness Alliance of MN, Canada-Minnesota Business Council, French-American Chamber of Commerce Key Opinion Leader for LifeSciences
  - Clients in the US, Canada, Norway, Sweden, Denmark, Iceland, Germany, Japan
- Business Associates:
  - Former Blue Cross and Humana Medical Directors for New Tech Assessment / Payer Relations
  - Certified Professional Coding for Hospital, Professional, DME and Supplies
  - Biostatisticians, Health Economists, Published Experts
  - European and Asian Market Consulting Partners

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Part I – Health Policy

"ObamaCare"

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A Tradition of Fee-For-Service

- Hospitals get a predetermined payment for inpatient (DRGs) and outpatient care (APCs), but there is excess hospital capacity
- Most physicians are in private group practices and they get paid for each discreet service they provide consequently costs are driven more by increasing utilization than by increasing cost per service
- The cost of care can vary greatly for patients across the country depending on physician practice style and access to healthcare resources
- US healthcare is largely supply-side driven

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Hard Realities

- 50 million Americans do not have health insurance
- Costs continue to rise about 6.5% per year (2014 projections) which is unsustainable
- The Medicare Trust Fund will be insolvent in 11 years, unless changes are made
- There aren't enough primary care physicians to manage an aging population under the current system
- Overall quality of care is below other countries (most Americans don't believe this)
- *"1/3rd of healthcare expenditures – an estimated $750 billion – don't improve health"**

* Institute of Medicine of the National Academies, Sept. 12, 2012

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Patient Protection and Affordable Care Act of 2010 (“ObamaCare”)

- Creates several new programs with the goals of:
  - Covering 50 million uninsured Americans
  - Improve the quality of care
  - Make healthcare less expensive/more affordable
- Cornerstone legislation for President Obama – the success or failure of healthcare reform will shape the White House and Congress in the next election

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Health Care Delivery Reform

- Accountable Care Organizations (ACOs) – legal structures between hospitals, physicians, and others that allow them to contract with government and private payers for risk-based payments
  - Designed to compel hospitals and physicians to work together better
  - Over 500 ACOs have already been formed – this has significant implications for the manner in which technology is sold to hospitals
  - ACOs have led to more hospitals buying out physician practices making them employees – a radical shift for many physicians

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Physician Worries About US Healthcare

- 90% said that their greatest concern with episode-based care is receiving inadequate payment and being penalized for factors that are out of their control
- 66% of surveyed physicians and hospitals believe they will become more integrated in the next 1 to 3 years

- 31% of physicians give the overall health care system an "A" for performance
- 57% of physicians said the practice of medicine is in jeopardy

Deloitte 2013 Survey of U.S. Physicians:
Physician perspectives about health care reform and the future of the medical profession; May 2013

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Part II - Reimbursement

- 3 Fundamentals
  1. Coding
  2. Payment
  3. Coverage

Reimbursement Fundamentals

- Coding – Is there a HCPCS (Healthcare Common Procedure Coding System) code that describes your device or the manner in which physicians will use it?
- Coverage – Do Medicare and most private insurers cover the procedures your devices permit and if so, under what clinical circumstances?
- Payment – Will physicians and hospitals be paid enough to encourage product adoption without being too expensive thereby discouraging government and private insurance coverage?

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CPT™ (Current Procedural Terminology)

- Every physician service is described by a CPT code either by a unique code or by a code representing a common group of services
- The AMA controls issuance of CPT codes
  - A panel of 23 people (mostly physicians) determines what services or procedures get unique new codes
    - The process is supported by medical societies representing specialty groups of orthopedists, cardiologists, family practice physicians, urologists, etc.
    - The process is only semi-transparent, largely subjective and physicians and payers take it very seriously
  - CPT code examples:
    - #27130 – Arthroplasty, femoral prosthetic replacement ("total hip")
    - #27280 – Arthrodesis, sacroiliac joint (including obtaining graft)
    - #73721 – Magnetic Resonance Imaging (MRI) any joint, lower extremity

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ICD -9 Diagnosis and Procedure Codes

- There are about 13,000 diagnosis codes in ICD-9: ICD-10 will have 74,000 diagnosis codes (Oct 2014)
- Diagnosis code examples
  - 250.0 – Diabetes mellitus without mention of complication
  - 411.81 – Acute coronary occlusion w/o myocardial infarction
  - 558.1 – Gastroenteritis and colitis due to radiation
- Procedure Codes (hospitals use these, physicians use CPT)
  - 16.1 – Removal of penetrating foreign body from eye
  - 35.20 – Replacement of unspecified heart valve
  - 49.41 – Reduction of hemorrhoids

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New CPT Code Criteria from AMA

- The service/procedure has received approval from the FDA for the specific use of devices or drugs;
- The suggested procedure/service is a distinct service performed by many physicians/practitioners across the United States;
- The clinical efficacy of the service/procedure is well established and documented in U.S. peer review literature;
- The suggested service/procedure is neither a fragmentation of an existing procedure/service nor currently reportable by one or more existing codes; and
- The suggested service/procedure is not requested as a means to report extraordinary circumstances related to the performance of a procedure/service already having a specific CPT code.

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Reimbursement Fundamental #2: Payment

Today hospitals and physicians get paid differently – but this is changing

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Hospital Payment Methodology

- DRGs (Diagnosis Related Groups) are the predominant method for paying for <u>inpatient hospital services</u>
  - There are about 900 DRGs to which any medical or surgical admission will be assigned based on patient diagnoses, procedures and the predetermined resources it should require to care for the average patient
  - Each DRG has a "weight" that is multiplied by a conversion factor to determine payment
  - <u>New Tech Pass Through Payment</u> allows the cost of new tech to be paid at/near retail cost for a period of two years if it meets a cost threshold and achieves "substantial clinical improvement"
  - Hospitals will adopt less expensive technologies because their revenue is fixed

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Physician Payment Methodology

- RBRVS (Resource Based Relative Value System)
  - Every CPT code is assigned a Relative Value Unit which is reflective of the physicians'
    - Work Expense (the skill, time, and decision making required for the procedure)
    - Practice Expense (assuming costs for a specific procedure including tech costs)
    - Malpractice Expense
  - The Relative Value Unit (RVU) is then multiplied by a Conversion Factor

	RVU		Conv Factor		Allowance
CPT #27130:	42.7	x	$34.0230*	=	$1,453
CPT #27280:	30.92	x	$34.0230*	=	$1,052
CPT #73721:	8.33	x	$34.0230*	=	$ 283

- RVUs are consistent among government and private payers
- Conversion Factors, consequently allowances, vary by payer

* The Medicare Conversion Factor for 2013

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New Payment Models are Coming

- Bundled Payments (hospital and physician combined)
- Value-Based Payments (will redirect payments from some hospitals to others based on pre-determined clinical outcomes)
- Risk Share Arrangements with ACOs for managing defined populations of Medicare and private insureds
- Payers want <u>Value</u> over Volume of Services

Value = Cost/Quality

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Reimbursement Fundamental #3 - Coverage

Not all services that are coded are covered

Payer Attitude of New Technology

"We can't be seduced by all of the wonderful technology toys and other stuff, because every good idea ain't good. At the end of the day, you have to ask yourself,

- *Does the technology work?*
- *Will it improve quality?*
- *Help manage costs?*
- *Be good for the consumer?*
- *Meet a real need? "**

* Reed Tuckson, M.D., executive VP and chief of medical affairs, UnitedHealth Group, December 7, 2010 LifeScience Alley Annual Meeting and Expo

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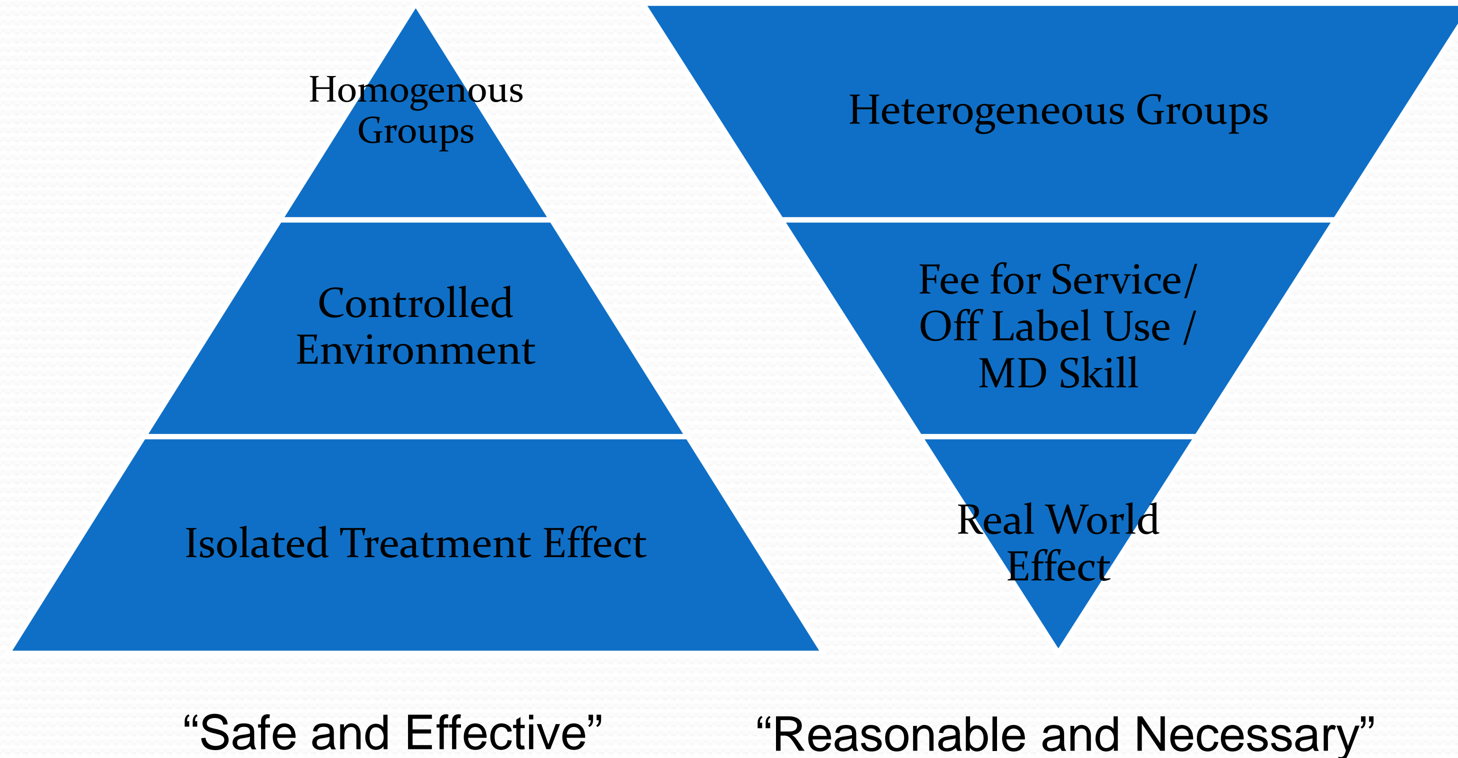
FDA vs. CMS Criteria



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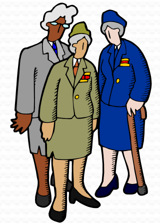
Who Pays For Healthcare in the US?

- US Government
  - Medicare – over age 65 (22% of national spending)
  - Medicaid – poor population
  - Military (TRICARE and Veterans Affairs for military)
- Private Insurers (about 1,100 insurance companies)
  - Employers – most insurance is purchased for employees
  - Individual health insurance
- Uninsured (50 million Americans)



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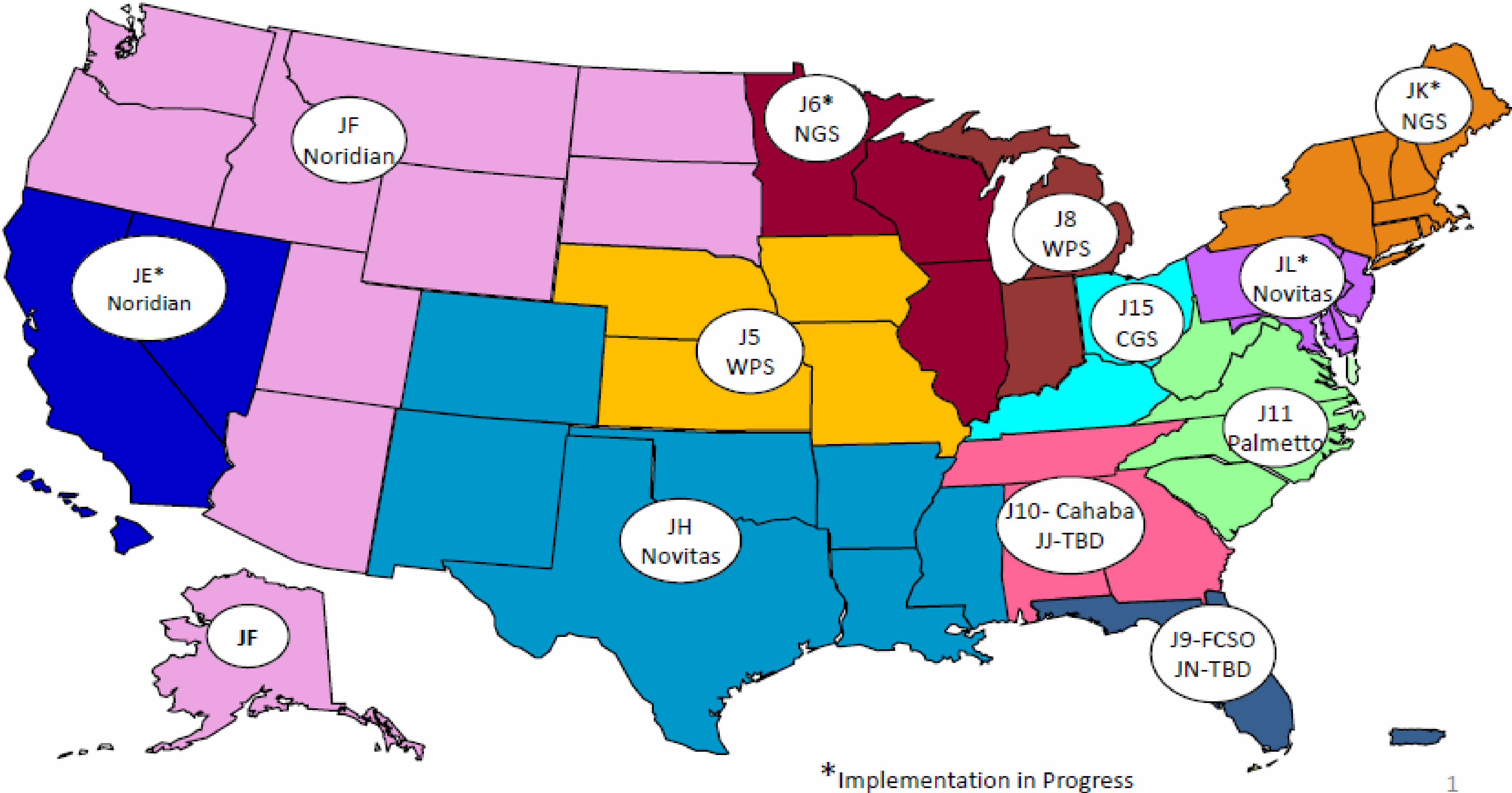
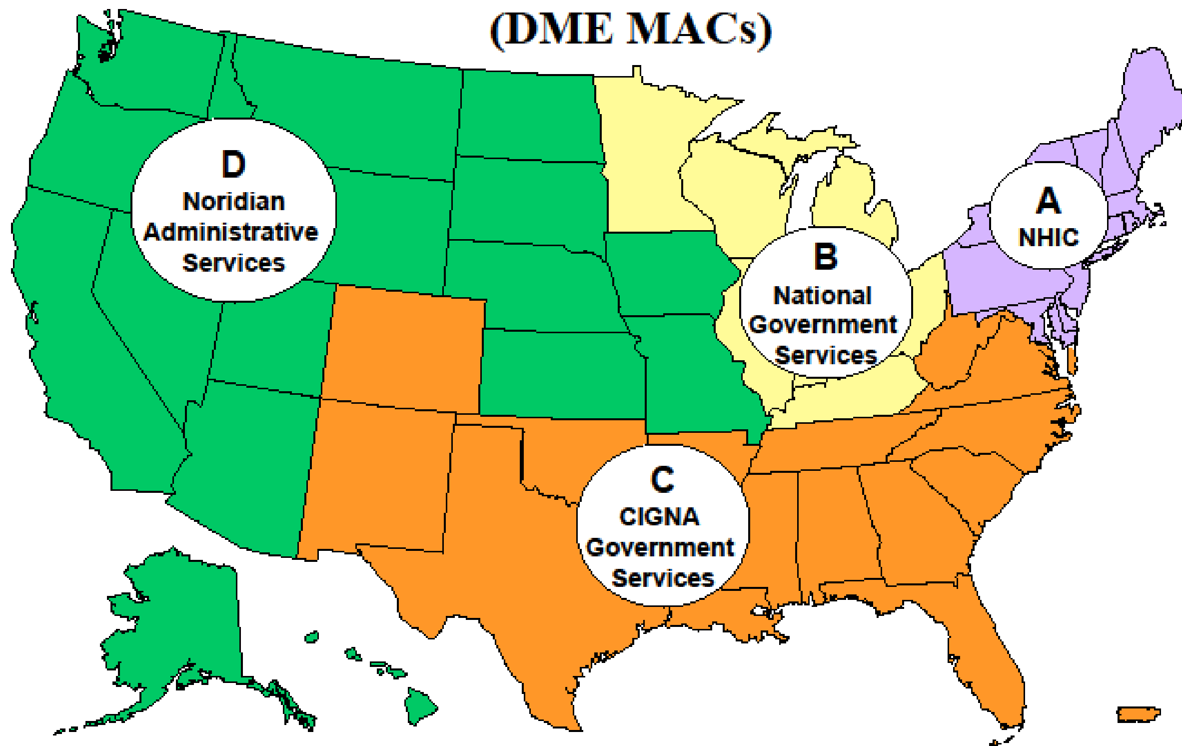
A/B MAC Current Jurisdictions



Medicare Jurisdictions-DME/POS



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Health Insurance

- Medicare is the largest single payer
  - Private insurers often, but not always, follow Medicare coverage decisions
  - Medicare, Medicaid, TRICARE and VA (government payers) all pay less than private insurers for the same services
- There are about 1,100 private health plans
  - Most private payers make their own coverage decisions
  - They also have varying payment levels, but they pay more than government payers

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Coverage Decision Making Isn't Perfect

- Private Payers, like Medicare, will rely primarily on the following for coverage decisions:
  - Peer-reviewed, published clinical literature
  - Evaluation of evidence for safety and efficacy
  - Support from physician community including medical societies and key opinion leaders
  - Documented cost-effectiveness
- Note: Every medical policy person views the same evidence differently thereby yielding different coverage decisions (even within government payers)

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You Must Market to Payers

- **Clinical Trials for Reimbursement** – the design of clinical trials that show cost substitution or savings
- **Health Economic Analyses** – Cost Effectiveness, Cost Minimization, Cost Substitution Studies
- **Product (also referred to as a "Clinical") Dossier** to describe how your technology works, the patients who will benefit from it, its intended use, summary of clinical support, FDA clearance – why payers should cover it
- **Payer Relations Campaign** – a strategy to use dossiers, published studies and payer relations experts to convince payers to cover your technology targeting markets in concert with your product Marketing/Sales plan. It will stratify the payers of choice in the regions most likely to be successful

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Reimbursement Pathways

- Your pathway to getting paid may be easier (or harder) than you think
  - Novel Devices – longer process for reimbursement, with greater risk/reward opportunities
  - Predicate-based Devices – reasonable process for reimbursement with moderate risk/rewards
  - Conventional Devices – a reimbursement pathway for your device may already exist; this can either very good or very bad

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Assessment vs. Strategy

- A Reimbursement Assessment is the first step in understanding how to monetize your technology. It is an analysis of existing Coding, Coverage, and Payment issues that will affect your device.
- A Reimbursement Strategy follows. It is the set of business decisions about how to navigate any business barriers uncovered as a result of the Assessment (in medical terms, think of an Assessment as the diagnosis and the Strategy as the treatment plan)

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Thank You

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