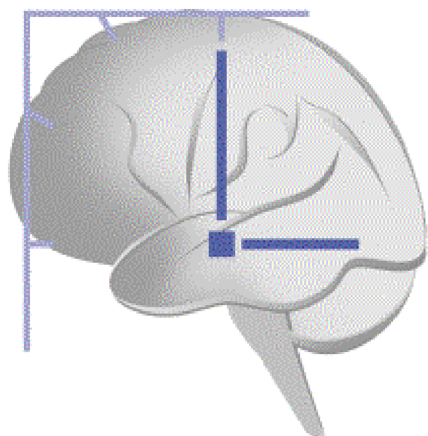

Stroke Management Group

a Johnson & Johnson initiative

Stroke Reimbursement Meeting
November 17, 2004

"There is no silver bullet for treating stroke."

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Introduction and Objectives

Stroke Management Group

Baseline all parties on stroke reimbursement information

- CMS decision making – policy change process
- Reperfusion therapy in AIS – clinical benefit
- Health Economics of AIS medical therapy

Discuss and Review Preliminary DRG Strategy

- Review prior CMS discussions (I.e., BAC)
- Develop potential contingency strategies/back-up positions

Prepare and discuss next steps for CMS meeting on December 9th

Physician Reimbursement

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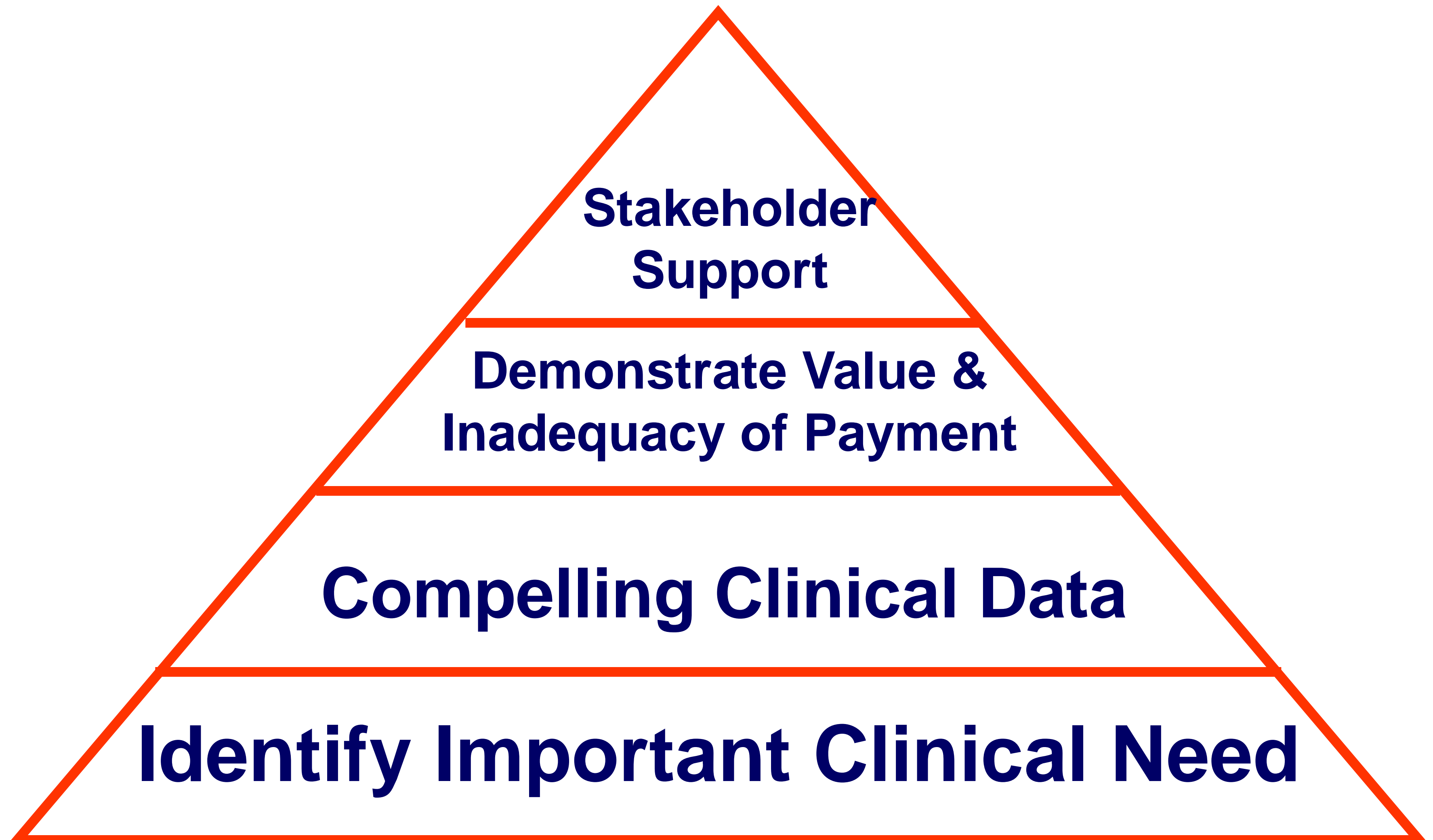
Criteria for Change or Modification of Reimbursement

Stroke Management Group



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The Four Essentials of Reimbursement

Stroke Management Group

- **Coverage** **(Medicare 5% National / 95% Local)**
- **Coding**
- **Payment**
- **Medical Necessity** **(Documentation)**

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The Four Essentials of Reimbursement

Stroke Management Group

- **Coverage**
- Coding
- Payment
- Medical Necessity (Documentation)

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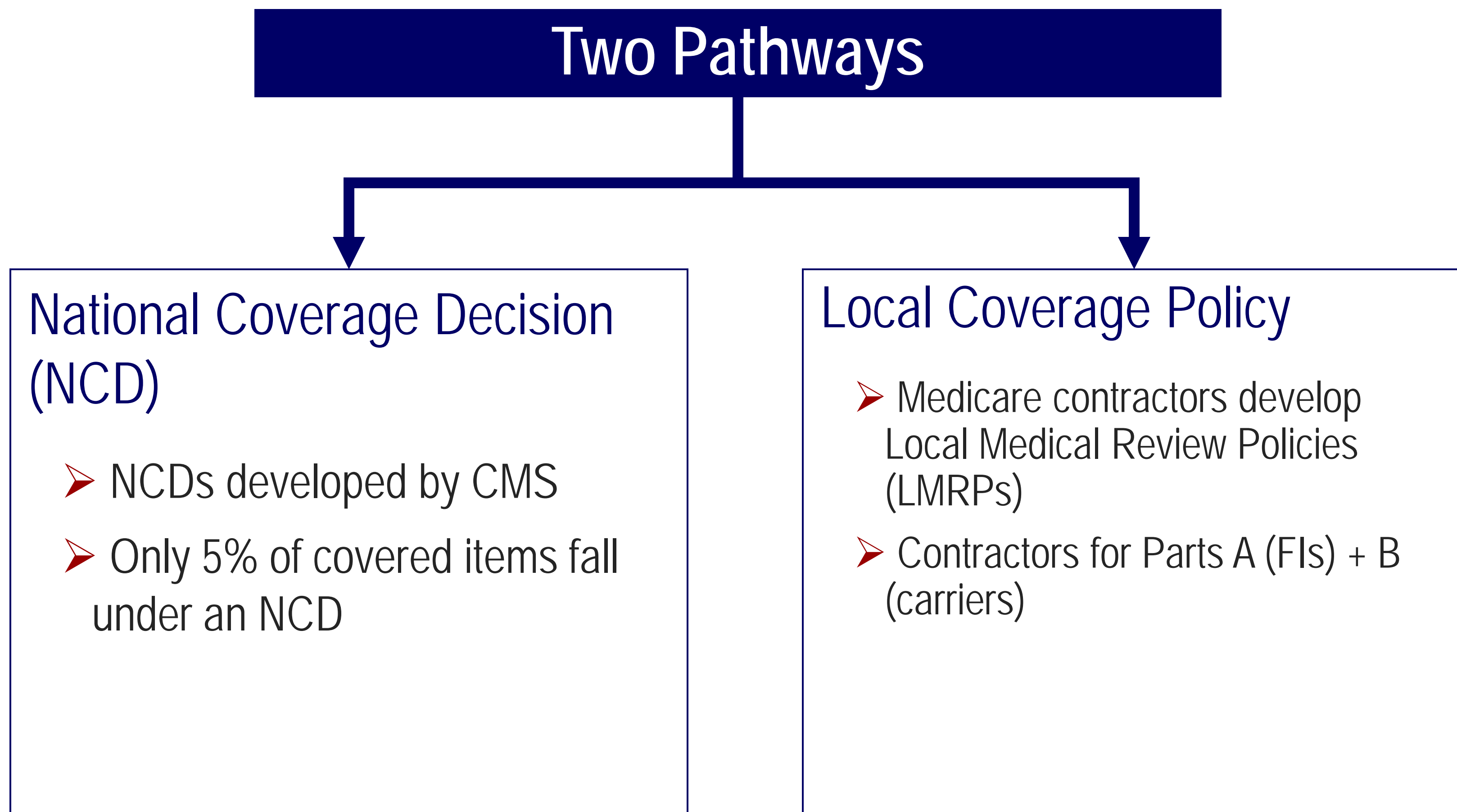
Coverage:
Medicare Coverage Decisions



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Coverage:
How Does CMS Apply "Reasonable and Necessary" Today?

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Sufficient level of confidence that **evidence is adequate** to conclude that the item or service:

- improves net health outcomes
- generalized to the Medicare population

Evidence assessed using standard principles of evidence-based medicine (EBM)

- **hierarchy of evidence** reduces "bias"

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Coverage:
Coverage Advisory Group Evidence Sources

Stroke Management Group

Literature Review (Peer-review)

Technology Assessment

Medicare Coverage Advisory Committee (MCAC)

Evidence-Based Guidelines

Professional Society Position Statements

Expert Opinion

Public Comments

Future Research

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Coverage:
Hierarchal Quality of Evidence

• Prospective	vs.	retrospective studies
• Randomized	vs.	observational studies
• Concurrent	vs.	non-concurrent comparisons
• Large studies	vs.	small studies
• Blinded	vs.	unblinded observers
• Effectiveness	vs.	efficacy (Practical Clinical Trials)
• Functional	vs.	technical outcomes

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The Four Essentials of Reimbursement

Stroke Management Group

- Coverage
- **Coding**
- Payment
- Medical Necessity (Documentation)

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Coding

Stroke Management Group

- Facility: ICD-9 Codes
  - ✓99.10 – Injection or Infusion of Thrombolytic Agent
  - ✓99.20 – Injection or Infusion of Platelet Inhibitors
- Physician – CPT Code 37195

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The Four Essentials of Reimbursement

Stroke Management Group

- Coverage
- Coding
- **Payment**
- Medical Necessity (Documentation)

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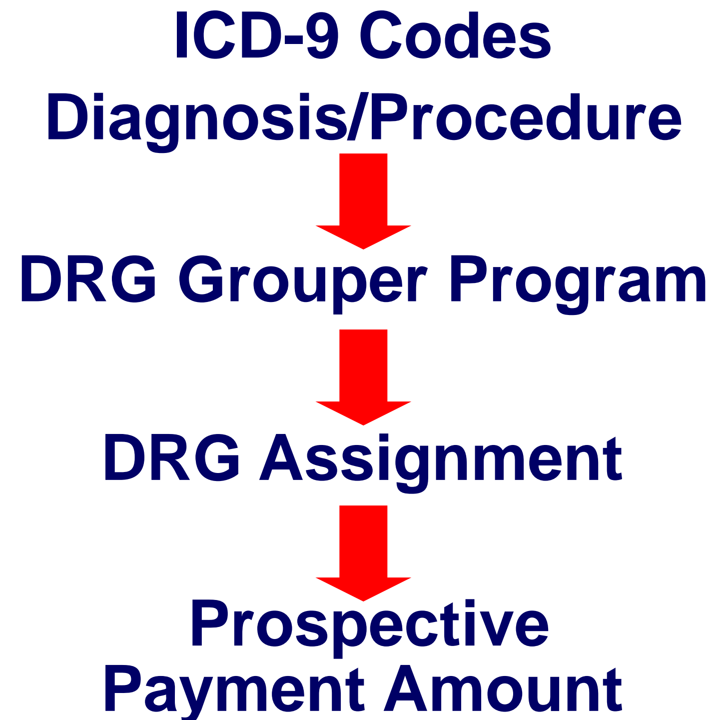
Stroke Management Group

The Medicare Reimbursement Process



Hospital Payment :
DRG Assignment Criteria

Stroke Management Group

- **Clinical Similarity**
- **Resource Consumption**

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Hospital Payment :
DRG's for Cerebrovascular Disorders

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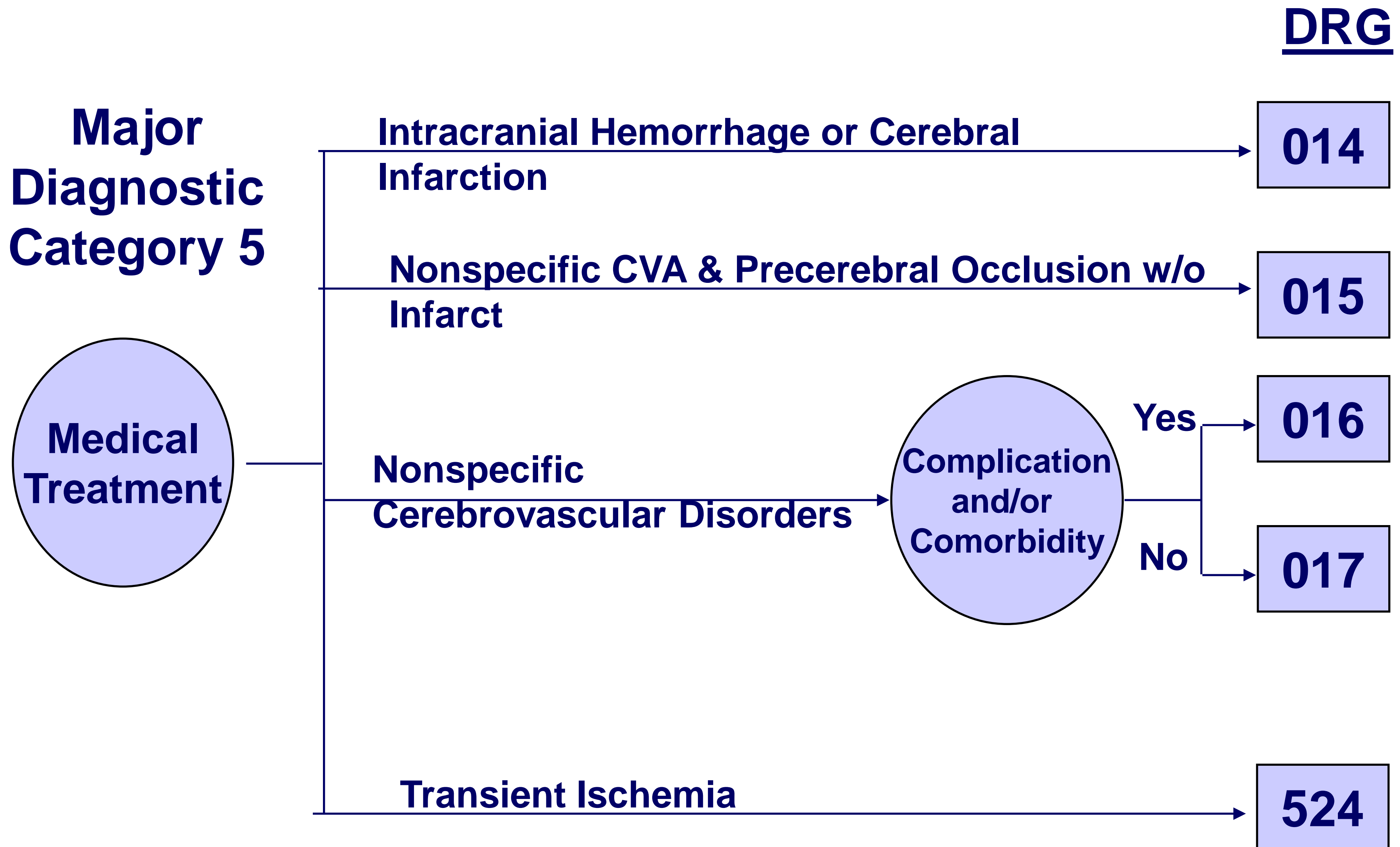

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Hospital Payment :
Intracranial Hemorrhage or Cerebral Infarct

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FY 2005

Principal Diagnosis:

434.01 Cerebral thrombosis, with infarct

Principal Procedure:

99.10 Infusion of thrombolytic
+/-
99.20 Infusion of platelet inhibitor
+/-
88.41 Angio of Cerebral Artery

DRG 014	$6,300

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Hospital Payment :
Nonspecific CVA & Precerebral Occlusion w/o Infarct

FY 2005

Principal Diagnosis:

434.10 Cerebral Embolism w/o Infarct:

Principal Procedure:

99.10 Infusion of thrombolytic
+/-
99.20 Infusion of platelet inhibitor
+/-
88.41 Angio of Cerebral Artery

DRG 015 $4,700

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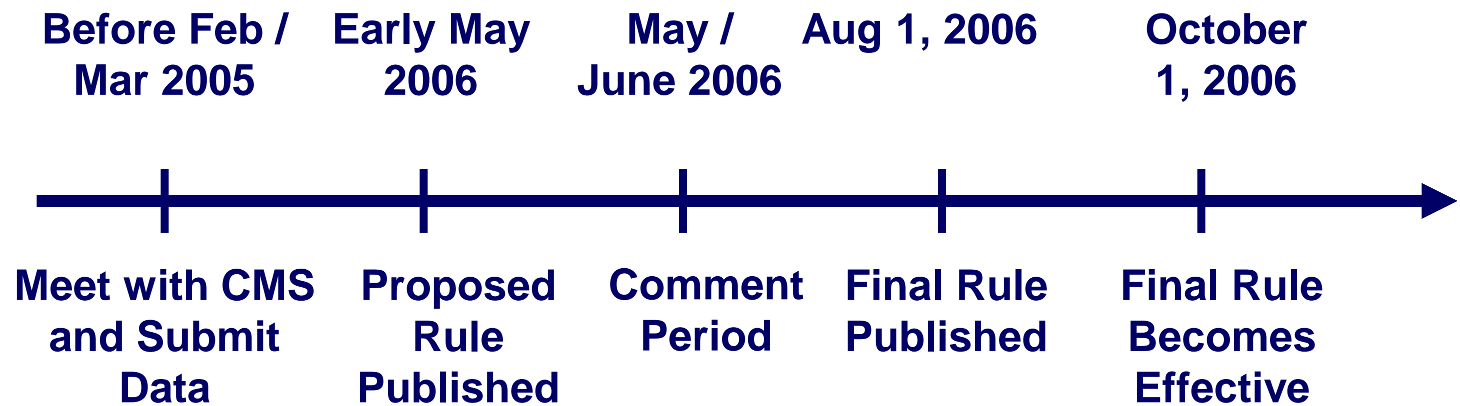
DRG Process & Timing

Stroke Management Group



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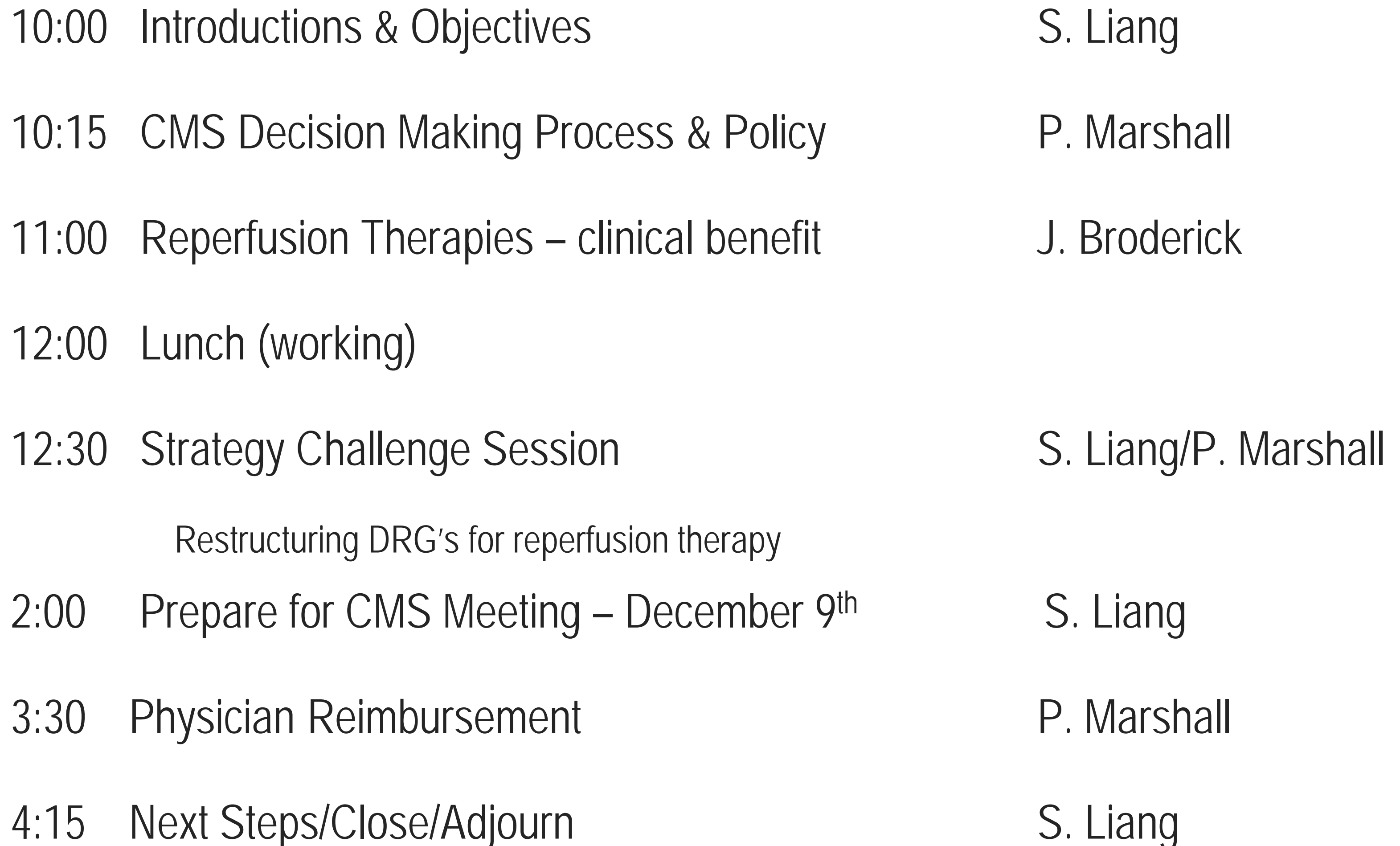
Agenda



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Reperfusion Therapies

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Clinical benefit

Amount of clinical evidence (NINDS, etc…)

Health Economic Studies/papers regarding improved outcomes

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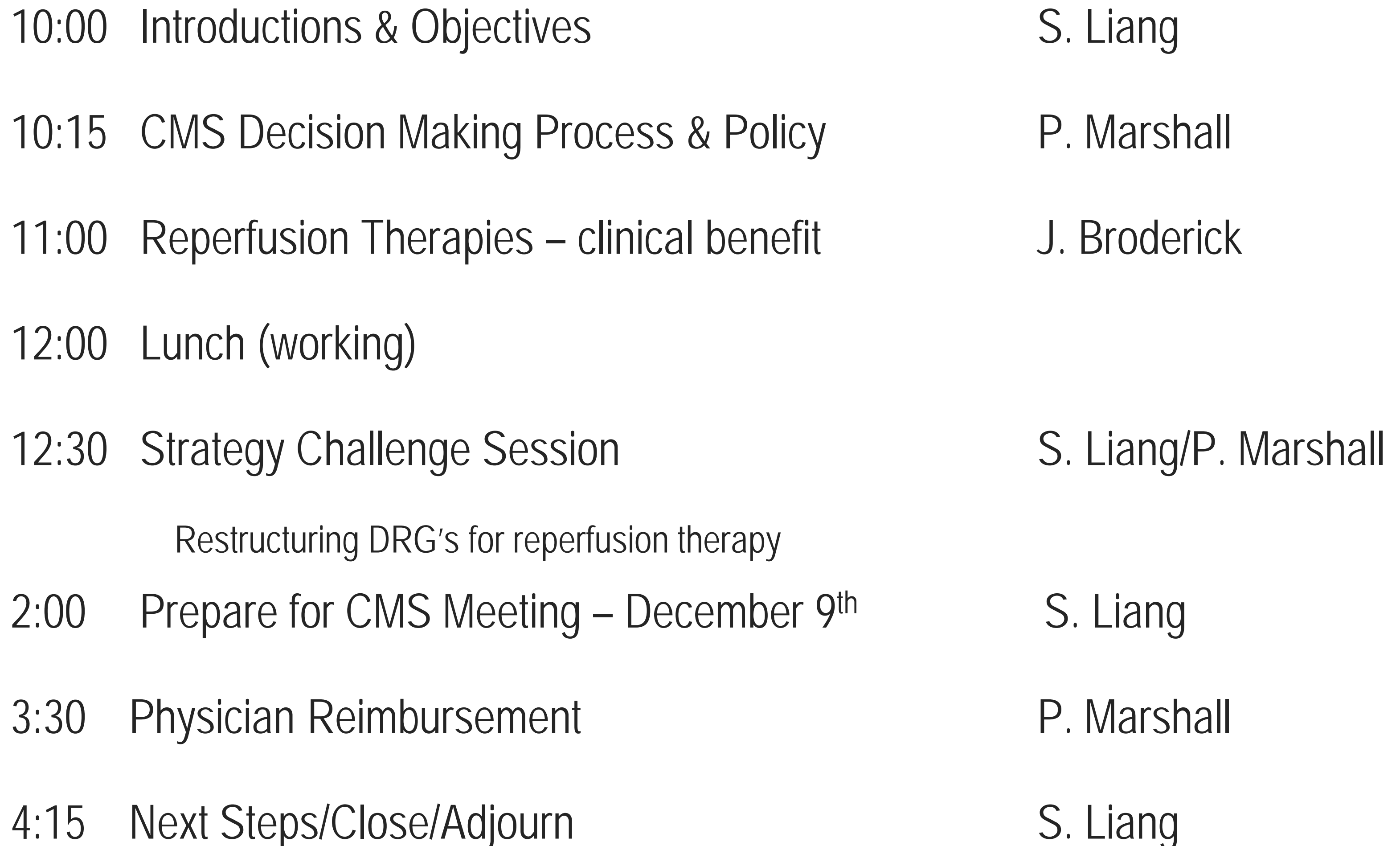
Agenda

Stroke Management Group



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Reimbursement Strategy

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- Current Health Economics – AIS
- Review Proposed Strategy
- Review Past Discussions – conference call with Dr. Brass
- Discuss/revise current plan
- Develop contingencies

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Stroke Management Group

J&J STROKE REIMBURSEMENT OBJECTIVES

To assess and impact the entire reimbursement landscape for stroke treatments along the following dimensions:

- **Acute Treatment – Ischemic and Hemorrhagic and TIA's**
- **Prevention and Recovery Therapies**
- **Medical Therapy (Pharma)**
- **Interventional (Surgery / Minimally Invasive – Catheter Based)**
- **Insurers: CMS and Private Payors**
- **Physicians payments (assist in policy change)**

As a first priority, focus is on Acute Treatment – Medical Therapy

Rationale: Can impact the largest amount of patients and hospitals and is currently woefully lacking

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OBJECTIVES:
ISCHEMIC STROKE AND REPERFUSION REIMBURSEMENT

Stroke Management Group

For Discussion

There are three primary objectives for Medicare I/P reimbursement for ischemic stroke:

Today's Focus

1. **Improve the current Medicare reimbursement payment for treating ischemic stroke with a reperfusion agent by restructuring DRG's**

2. **Lay foundation for the potential that other reperfusion agents such as ReoPro can benefit from an improvement in the inpatient payment changes for ischemic stroke – broadening the definition of treatment to 'reperfusion agents'**

3. **Lay foundation so that in the future with additional data, prospective payments for the treatment of ischemic stroke can be increased**

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CURRENT SITUATION
ISCHEMIC STROKE REIMBURSEMENT*

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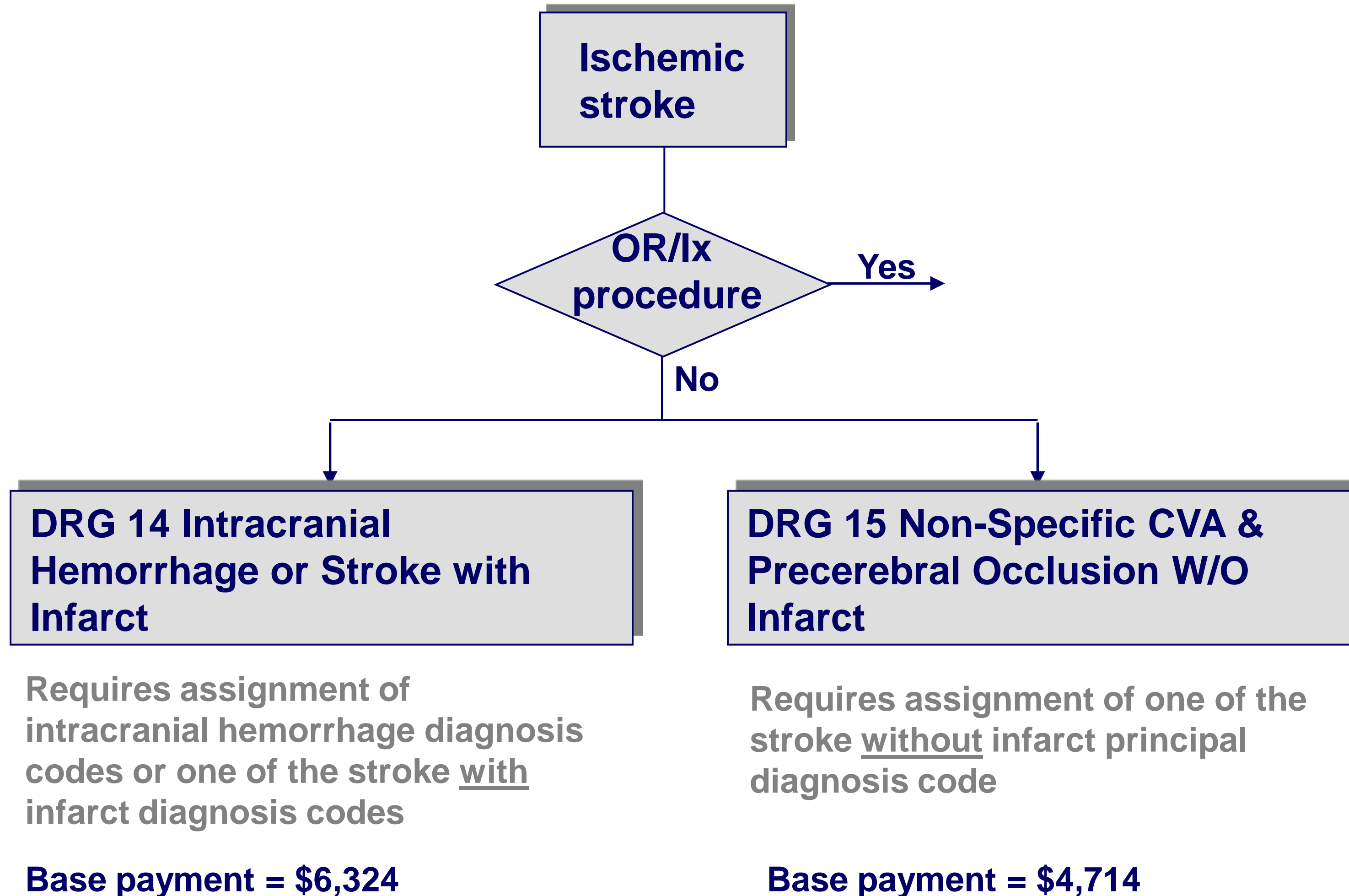
Ischemic stroke patients who do not receive a procedure are assigned to one of two possible DRGs based on principal diagnosis…



*Medicare reimbursement

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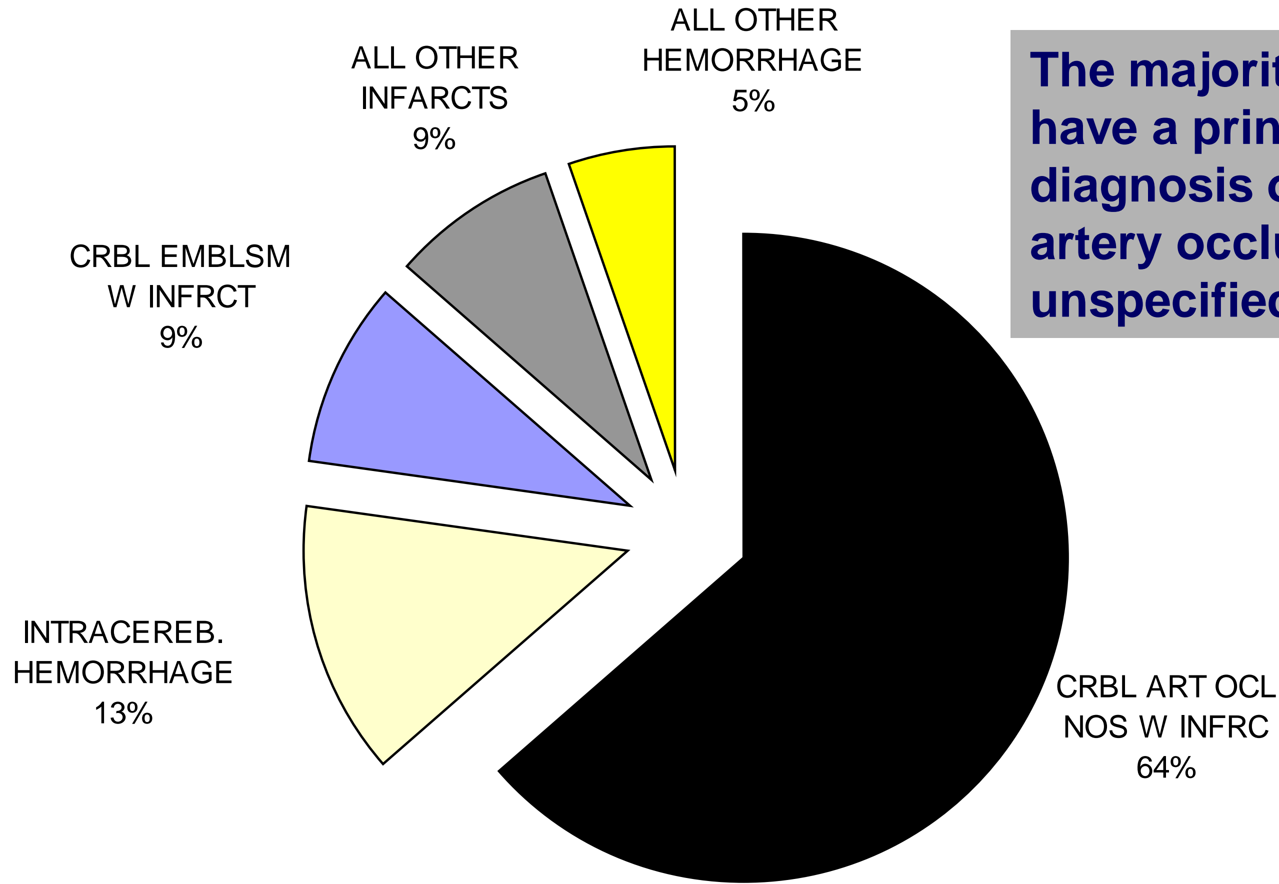
CURRENT SITUATION
STROKE PATIENTS BY PRINCIPAL DIAGNOSIS

Stroke Management Group

DRG 14 discharges by principal diagnosis



The majority of patients have a principal diagnosis of cerebral artery occlusion, unspecified

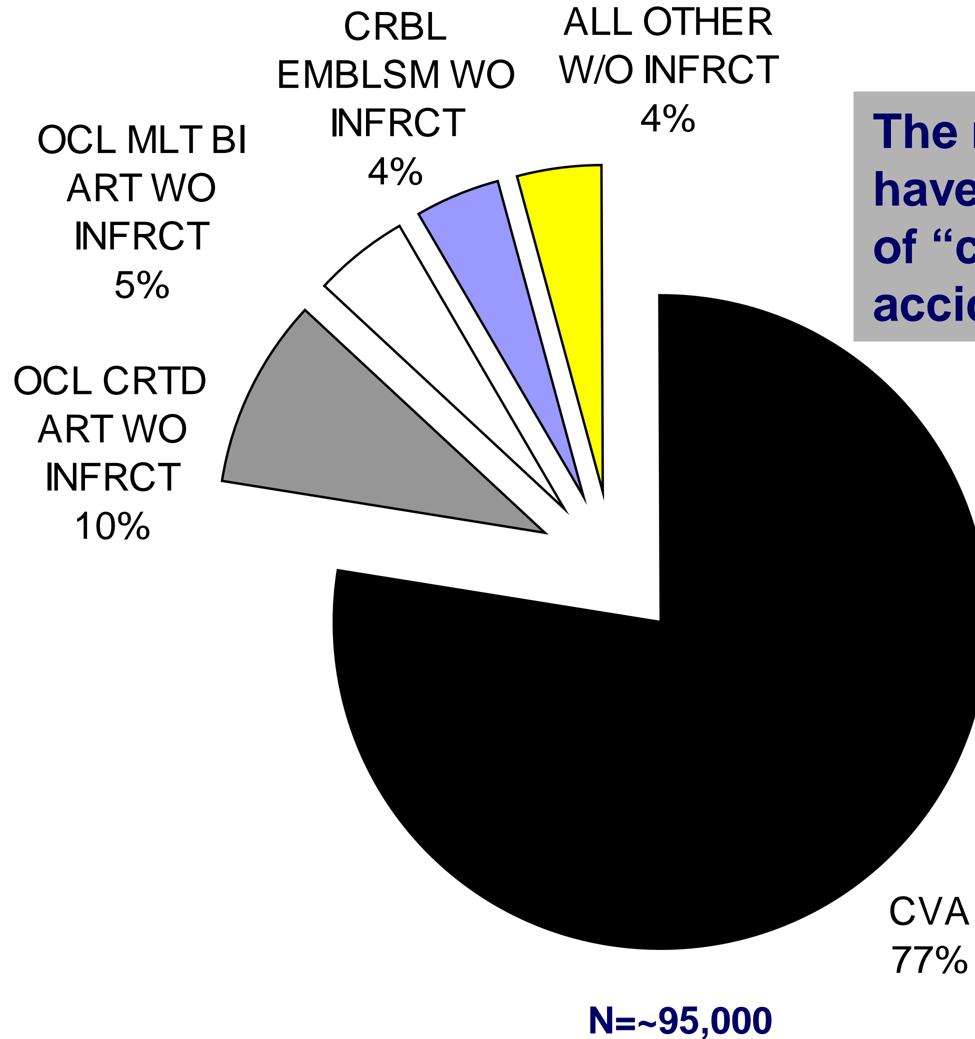
N=~256,000

Source: 2003 Medicare MedPAR data

CURRENT SITUATION
STROKE PATIENTS BY PRINCIPAL DIAGNOSIS

Stroke Management Group

DRG 15 discharges by principal diagnosis



The majority of patients have a principal diagnosis of "cerebrovascular accident"

N=~95,000

Source: 2003 Medicare MedPAR data

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Stroke Management Group

CURRENT SITUATION
HOSPITAL CHARGES FOR STROKE PATIENTS

Stroke patients who receive a thrombolytic agent have significantly higher in-hospital charges but are currently small in number…

Of all discharges in DRGs 14 & 15…	N	LOS Mean	Std. Charges Mean
Patients receiving a thrombolytic	2,452	6.9	$31,259
Patients not receiving a thrombolytic	321,757	5.5	$16,213

Source: 2003 Medicare MedPAR data. Thrombolytic patients coded with ICD-9 code 99.10.

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CURRENT SITUATION
DIFFERENCE IN HOSPITAL CHARGES BY COST CTR

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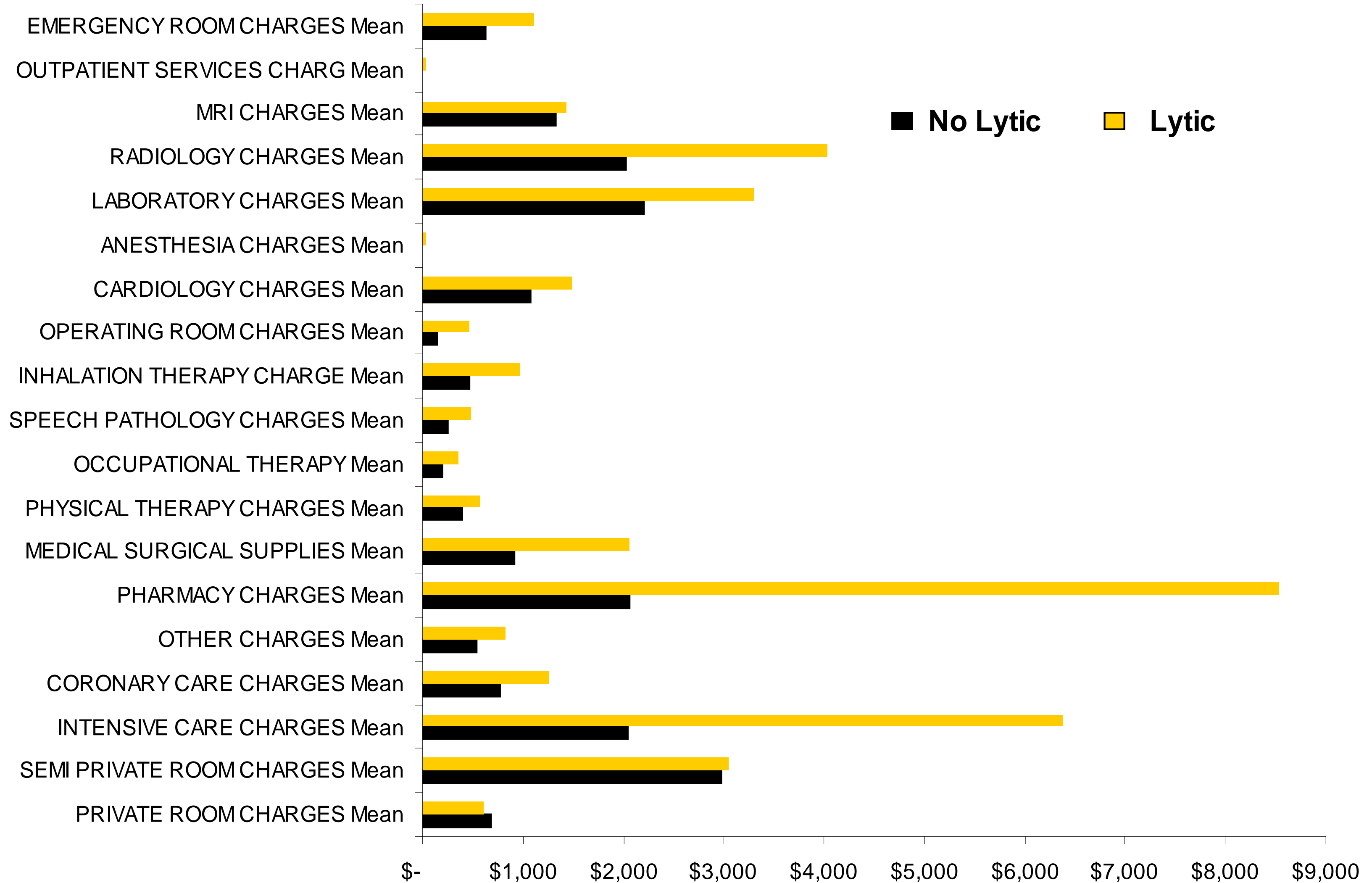
Pharmacy and ICU charges are driving the difference in resource use between the thrombolytic and non-thrombolytic group (in DRGs 14/15)…



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Reimbursement Strategy

Stroke Management Group

Objective: Improve the current Medicare reimbursement payment for treating ischemic stroke with a 'reperfusion' agent

Strategy overview:

What?

- Convince CMS that the current payment structure for ischemic stroke should change
- Ask CMS to re-structure DRGs to group stroke patients into one of two DRGs based on whether or not a patient received a reperfusion agent

Why?

- Re-grouping patients into these new DRGs would dramatically increase payment for patients treated with a reperfusion agent
- New higher paying DRG would encourage better patient care
- Re-structuring DRG's provides incentives to set up Stroke Centers

How?

- Help leading Stroke institutions and key stakeholders in preparation for meeting with CMS
- Assist leading Stroke institutions organize and build broad coalition

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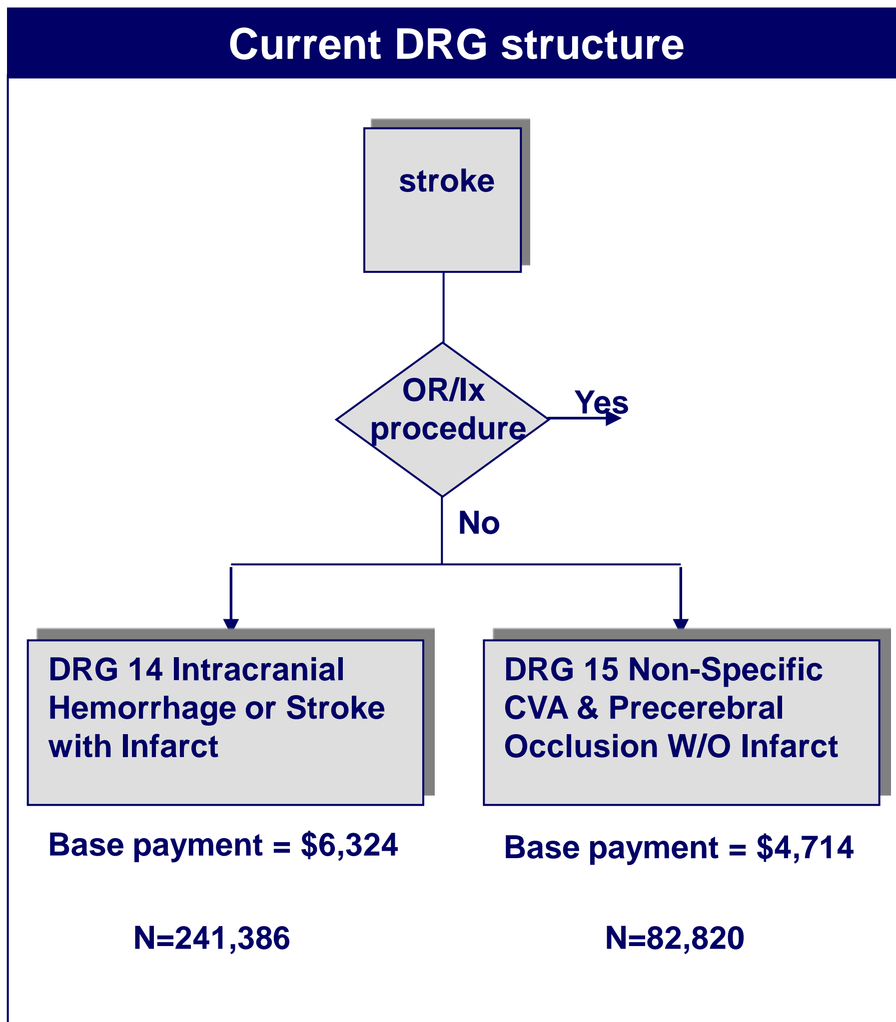
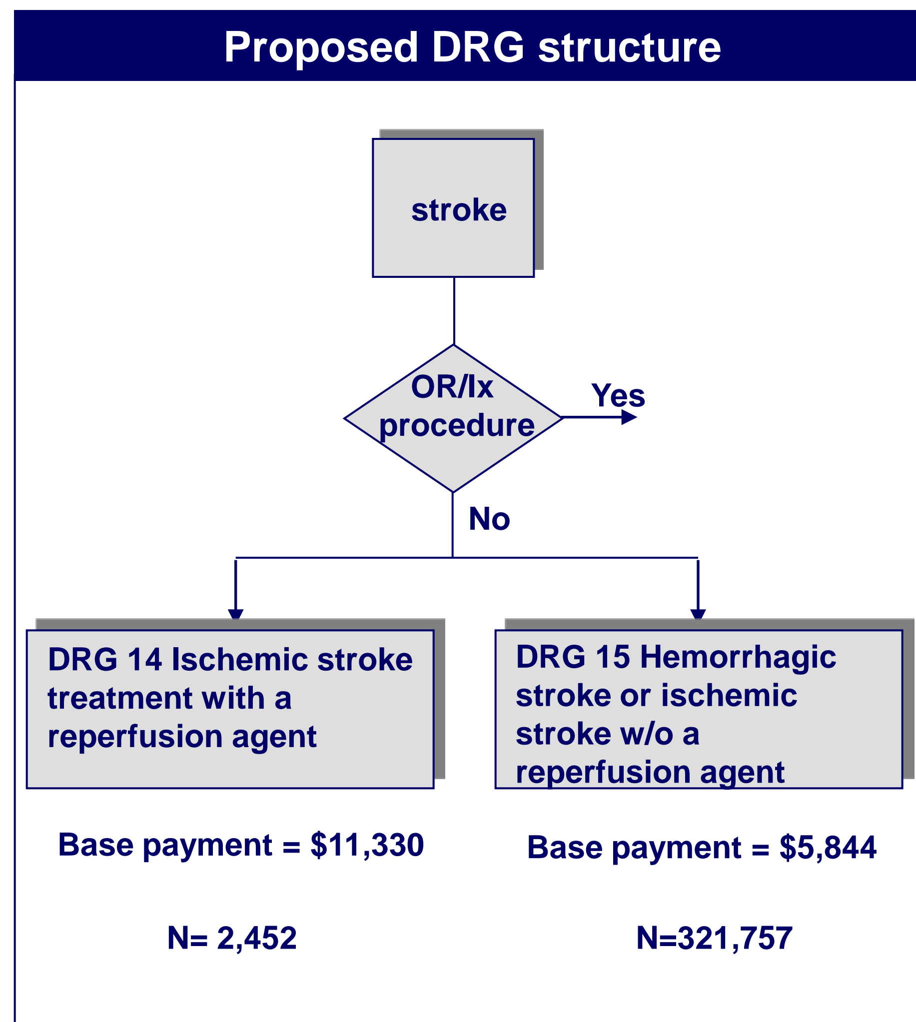
DRG Strategy

Restructure to improve incentives for aggresively treating stroke





*Medicare reimbursement: discharge totals are adjusted for transfer policy rules. Source: 2003 FY MedPAR data

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Strategic Challenges

Stroke Management Group

Issues:

Mitigating Steps:

1. Low volume of TPA cases
   - Tail Wagging the Dog
   - Must demonstrate clinical benefit outweighs potential harm in non-clinical trial setting (effectiveness vs. efficacy)
2. Hospitals will object to lower payment for treating infarct patients w/o TPA (majority of cases)
3. CMS will be reluctant to change from +/- infarct descriptions
4. Loss leader – why hospitals are pursuing JHACO certification?
5. Other stakeholders affected? (I.e., ER physicians, hospitals, etc)
6. Other issues

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Strategic Alternatives

Stroke Management Group

1. Request a new DRG for Cerebral Infarct with Administration of Reperfusion Agent
2. CMS will most likely not agree to assign cases to one of the OR / Cath lab DRGs 1, 2 or 528
3. Contingency back up plan for meeting
4. Alternative Suggestions

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CMS

Stroke Management Group

- What are the key messages
- Objectives of the meeting
- What does **"Success looks like?"**

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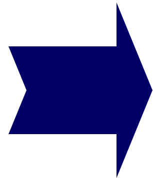
Agenda

Stroke Management Group

10:00	Introductions & Objectives	S. Liang
10:15	CMS Decision Making Process & Policy	P. Marshall
11:00	Reperfusion Therapies – clinical benefit	J. Broderick
12:00	Lunch (working)	
12:30	Strategy Challenge Session	S. Liang/P. Marshall
	Restructuring DRG's for reperfusion therapy	
2:00	Prepare for CMS Meeting – December 9th	S. Liang
3:30	Physician Reimbursement	P. Marshall
4:15	Next Steps/Close/Adjourn	S. Liang



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Next Steps – CMS Meeting

1. Identify CMS meeting attendees
2. Meet with CMS (Dec 9th) to review clinical outcomes data supporting use of TPA (best medical care)
   - Include data supporting other non-FDA approved drugs
   - Peer-review literature
   - Update re: ongoing clinical trials & FDA approval status
3. Provide reasons why TPA is infrequently used and why this will (should) change
4. Positions of medical societies
5. Data showing why DRG payments are inadequate
6. Discussion, feedback and next steps

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CMS Presentation
Create Strawman

Stroke Management Group

- Objectives
- Who are “we” representing?
- Case for change
  - Clinical data
    - AIS
    - Long term outcomes affecting improved recovery
- Case for Action
  - Options, etc
- Proposed next steps

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Next Steps – Post CMS Meeting

- Weekly conference calls
- Assess CMS response to clinical data and the need for a higher paying DRG assignment
- Finalize DRG recommendation and gather necessary data
- Arrange for a meeting with the CMS payment group to present DRG proposal
- Solicit support from KOL's and relevant medical societies
- Develop industry & PhRMA coalition
- Prepare Capital Hill strategy
- Assess support from hospital associations and hospital groups
- Letters to CMS pre & post Proposed Rule
- Add Stroke treatment to list of 10 Hospital Quality Initiatives

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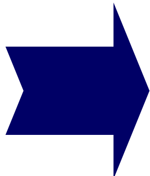

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Physician Payments
CPT Codes

Stroke Management Group

- American Medical Association
- CPT Editorial Board
- Assigns Physician CPT Codes

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Process For New CPT Codes

Stroke Management Group

CPT Editorial Panel

- typically meets 4 times/year
- about 15 voting members, including five organizational representatives: CMS, BCBS, HIAA, AHA, managed care representative
- FDA approval is prerequisite

Timing

- annual cycle
- long lead time: application deadline for January 1, 2005 was October 1, 2003

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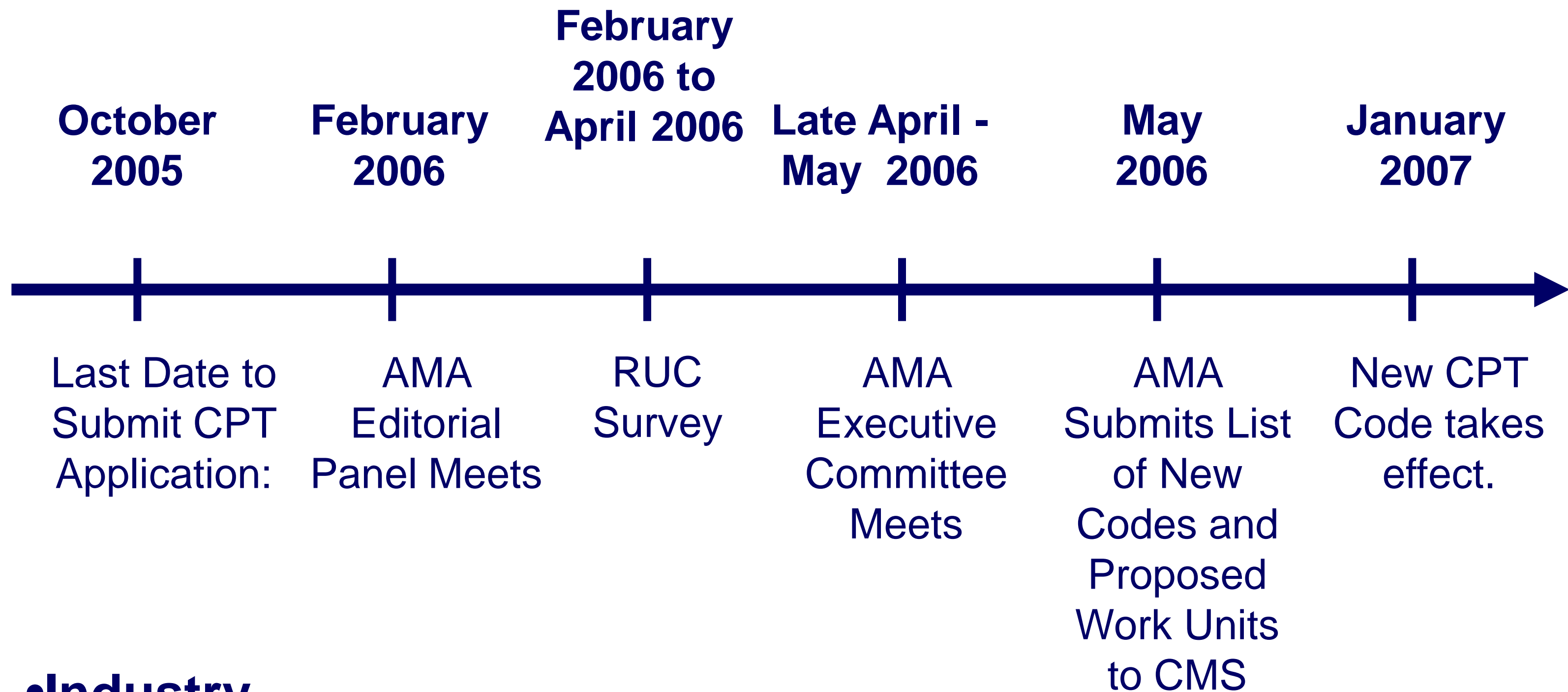
AMA CPT-4 Coding Process

Stroke Management Group



- **Industry**
- **Physician**
- **Medical Society**

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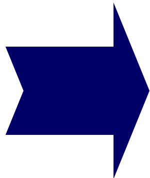

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Meeting Close

Stroke Management Group

Next steps…

Thank you.

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Back up

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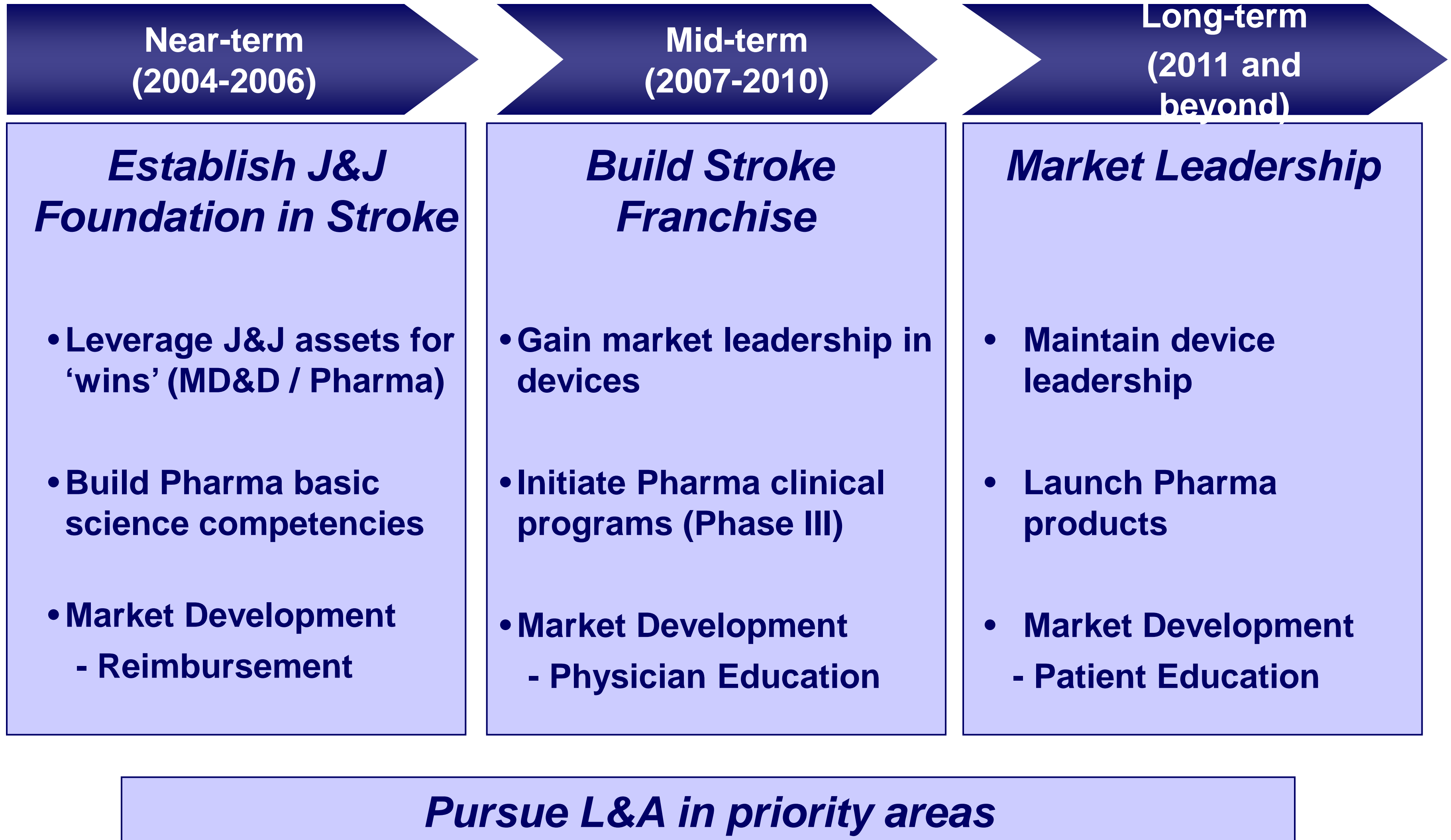
J&J Stroke Management Strategic Imperatives



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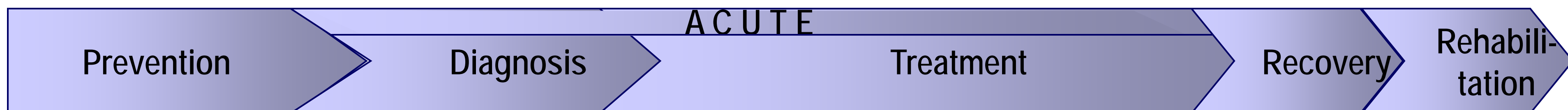
Treatment Options

Pharmaceutical and Medical Device Opportunities

Stroke Management Group



Current Therapies

- Atrial Fibrillation (AFib)
  - Anticoagulation (Warfarin)
  - Surgical and Ix AFib ablation
  - Left Atrial Appendage Closure
- Aneurysm treatment
  - Coils

- Acute diagnosis
  - Stroke differentiator (CT)

- Recanalization
  - Reperfusion agents (tPA)
- Aneurysm treatment

- Physical therapy

Future Therapies

- Intracranial Intervention
  - Angioplasty and stents
- Carotid stents
- Atrial Fibrillation (AFib)
  - Anticoagulation (Direct Thrombin Inhibitor)
- Embolic protection devices
- Patent Foramen Ovale (PFO) closure

- Acute diagnosis
  - Stroke identifier
  - Stroke patient sub-typing

- Cytoprotection
  - Drugs / Hypothermia / Perfusion
- Intracranial Intervention
  - Angioplasty and stents
  - Clot retrieval
- Recanalization
  - Reperfusion agents (ReoPro)
  - Reperfusion agent enhancers

Hemorrhagic Stroke – Novo 7

- Neuroregenerative
  - Drugs, stem cells
  - Devices
- Motion Restoration

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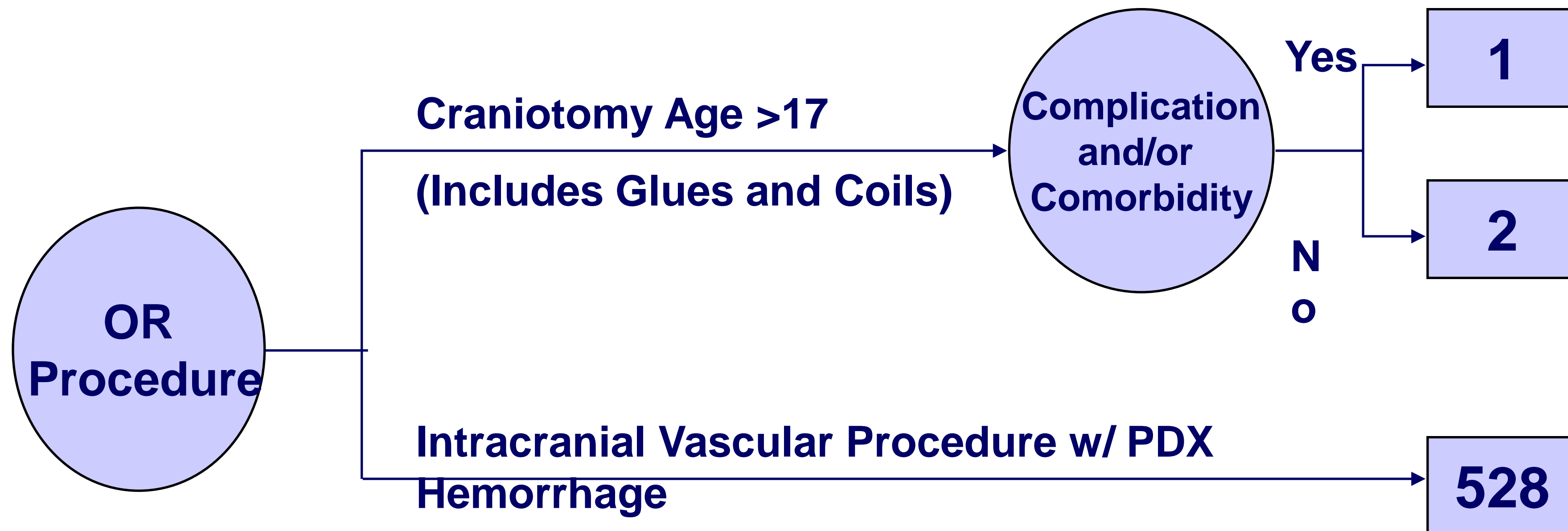
Major Diagnostic Category 5

Operating Room / Cath Lab Procedures (Includes Glues and Coils)

DRG



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Craniotomy Procedures

DRG	Description	Payment
001	Craniotomy Age >17 w/ cc	$16,600
002	Craniotomy Age >17 wo/ cc	$9,700
528	Intracranial Vascular Procedure w/ PDX Hemorrhage	$[illegible]4,000

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Nonspecific Cerebrovascular Disorder w/ CC

Hospital Coding

FY 2005

Principal Diagnosis:

437.0 Cerebral Atherosclerosis:

Principal Procedure:

99.10 Infusion of thrombolytic
+/-
99.20 Infusion of platelet inhibitor
+/-
88.41 Angio of Cerebral Artery

DRG 016 w/ cc	**$6,200**
DRG 17 w/o cc	**$3,500**

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Transient Cerebral Ischemia (TIA)

Hospital Coding

Stroke Management Group

FY 2005

Principal Diagnosis:

435.X Transient cerebral ischemia:

Principal Procedure:

99.10 Infusion of thrombolytic

+/-

99.20 Infusion of platelet inhibitor

+/-

88.41 Angio of Cerebral Artery

DRG 524 $3,700

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Stroke Management Group

Nonspecific Cerebrovascular Disorder w/ CC

Hospital Coding

FY 2005

Principal Diagnosis:

437.0 Cerebral Atherosclerosis:

Principal Procedure:

99.10 Infusion of thrombolytic
+/-
99.20 Infusion of platelet inhibitor
+/-
88.41 Angio of Cerebral Artery

DRG 016 w/ cc	**$6,200**
DRG 17 w/o cc	**$3,500**

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Transient Cerebral Ischemia (TIA)

Hospital Coding

FY
2005

Principal Diagnosis:

435.X Transient cerebral ischemia:

Principal Procedure:

99.10 Infusion of thrombolytic
+/-
99.20 Infusion of platelet inhibitor
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88.41 Angio of Cerebral Artery

DRG 524 $3,700

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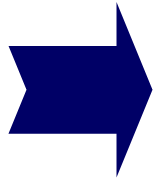
Agenda

Stroke Management Group



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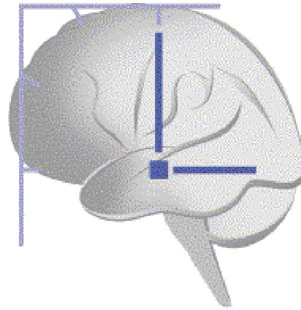

Stroke Management Group

a Johnson & Johnson initiative

Vision

Leading the global revolution against stroke

Mission

Improving outcomes through the prevention and treatment of stroke

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The J&J Credo

Stroke Management Group

The Four Tenets

Doctors, Nurses, Patients

Employees

Community

Shareholders

Our Credo

We believe our first responsibility is to the doctors, nurses and patients,
to mothers and fathers and all others who use our products and services.
In meeting their needs everything we do must be of high quality.
We must constantly strive to reduce our costs
in order to maintain reasonable prices.
Customers' orders must be serviced promptly and accurately.
Our suppliers and distributors must have an opportunity
to make a fair profit.

We are responsible to our employees,
the men and women who work with us throughout the world.
Everyone must be considered as an individual.
We must respect their dignity and recognize their merit.
They must have a sense of security in their jobs.
Compensation must be fair and adequate,
and working conditions clean, orderly and safe.
We must be mindful of ways to help our employees fulfill
their family responsibilities.
Employees must feel free to make suggestions and complaints.
There must be equal opportunity for employment, development
and advancement for those qualified.
We must provide competent management,
and their actions must be just and ethical.

We are responsible to the communities in which we live and work
and to the world community as well.
We must be good citizens -- support good works and charities
and bear our fair share of taxes.
We must encourage civic improvements and better health and education.
We must maintain in good order
the property we are privileged to use,
protecting the environment and natural resources.

Our final responsibility is to our stockholders.
Business must make a sound profit.
We must experiment with new ideas.
Research must be carried on, innovative programs developed
and mistakes paid for.
New equipment must be purchased, new facilities provided
and new products launched.
eserves must be created to provide for adverse times.
When we operate according to these principles,
the stockholders should realize a fair return.

Johnson & Johnson

Our Credo

We believe our first responsibility is to the doctors, nurses and patients,
to mothers and fathers and all others who use our products and services.
In meeting their needs everything we do must be of high quality.

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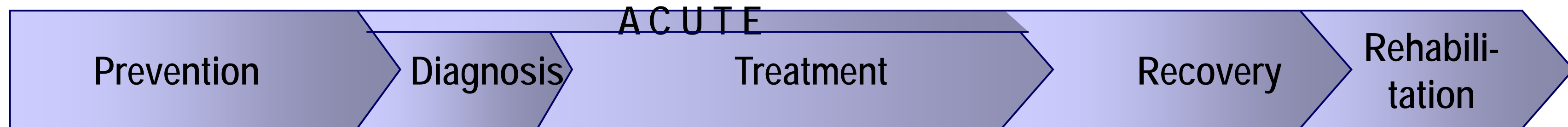
Stroke Competitive Landscape: Why Is J&J Equipped to Win in Stroke?

Stroke Management Group

NOT EXHAUSTIVE



Pharma Companies

- AZ
- Bayer
- BTG
- Lilly
- Abbott
- Emisphere
- Mitsubishi/GSK
- AG Scientific
- Forrest
- Genzyme
- Millenium
- Senju

J&J:

- McNeil Consumer
- Centocor
- Ortho Biotech
- Janssen
- PRD

Major Device Companies

- Boston

J&J:

- Biosense Webster
- Cordis Endovascular
- Cordis Neurovascular
- Cordis Cardiology
- CardioVations
- NDC
- OCD
- Codman
- Independence Technology

Start-ups

- AGA
- Atricure
- Atritech
- Cardima
- Solutions
- Epicor
- Microvention
- Micrus
- Mindguard
- WL Gore
- Biosite
- Omnicorder
- Alsius/eV3
- CSZ
- Microvention
- Paion
- Yamanouchi
- Afferent
- D-Pharm

J&J:

R&D / VC

- CBAT
- DED
- JJDC / COSAT

Market Development

- J&J Federal and State Affairs
- Reimbursement
- Consumer Marketing and Education
- Industry Associations – ADVAMED

"There is no 'silver bullet' in Stroke – a multi-disciplinary, multi-treatment approach is required"

"Only J&J can address the broad spectrum of treatments and develop the market to impact the outcomes of patient care on a global basis"

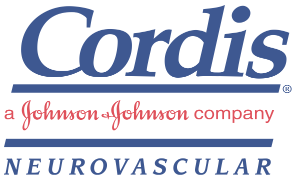
Stroke Management Participants

Pharmaceuticals

Diagnostics

J&J

Devices



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J&J Stroke Management Strategy Development Process

Stroke Management Group

Market Assessment

- Unmet needs
  - Prevention
  - Diagnosis
  - Treatment
  - Post acute care/recovery
- Market potential
- Individual product potentials
- Competitive landscape

Portfolio and market development

- Investment Screen/criteria
- Internal and external product opportunities
- SMG portfolio plan
- SMG market development

SMG business model

- Future vision
- Operating guidelines
- Virtual P&L
- Budget

Strategy Execution

- Strategy Management
- Global Study
  - Japan
  - Europe
  - CAPLA
- Recovery

ROW assessment supports our original recommendations

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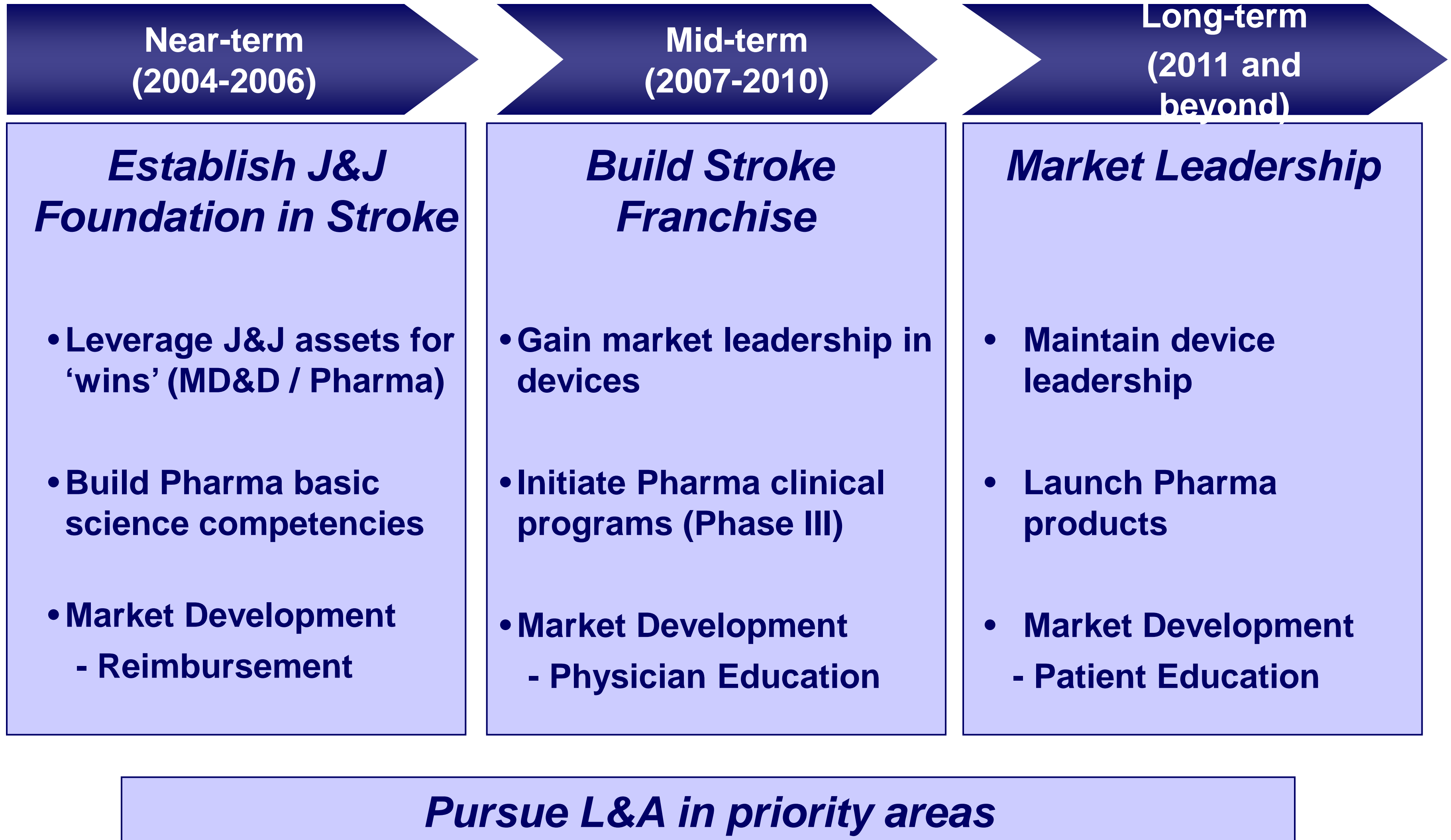
J&J Stroke Management Strategic Imperatives

Stroke Management Group



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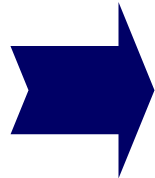
Agenda

Stroke Management Group



10:00	Introductions & Objectives	S. Liang
10:15	CMS Decision Making Process & Policy	P. Marshall
11:00	Reperfusion Therapies – clinical benefit	J. Broderick
12:00	Lunch (working)	
12:30	Strategy Challenge Session	S. Liang/P. Marshall
	Restructuring DRG's for reperfusion therapy	
2:00	Prepare for CMS Meeting – December 9th	S. Liang
3:30	Physician Reimbursement	P. Marshall
4:15	Next Steps/Close/Adjourn	S. Liang

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CMS Decision Making Process

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- Criteria/process for change
- Decision Makers
- Timelines

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