“There is no silver bullet for treating stroke.”
Introduction and Objectives

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
Criteria for Change or Modification of Reimbursement

- Identify Important Clinical Need
- Compelling Clinical Data
- Demonstrate Value & Inadequacy of Payment
- Stakeholder Support
The Four Essentials of Reimbursement

- **Coverage** *(Medicare 5% National / 95% Local)*
- **Coding**
- **Payment**
- **Medical Necessity** *(Documentation)*
The Four Essentials of Reimbursement

◆ Coverage
◆ Coding
◆ Payment
◆ Medical Necessity (Documentation)
Coverage: Medicare Coverage Decisions

Two Pathways

National Coverage Decision (NCD)
- NCDs developed by CMS
- Only 5% of covered items fall under an NCD

Local Coverage Policy
- Medicare contractors develop Local Medical Review Policies (LMRPs)
- Contractors for Parts A (FIs) + B (carriers)
Coverage:
How Does CMS Apply “Reasonable and Necessary” Today?

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”
Coverage:
Coverage Advisory Group Evidence Sources

- Literature Review (Peer-review)
- Technology Assessment
- Medicare Coverage Advisory Committee (MCAC)
- Evidence-Based Guidelines
- Professional Society Position Statements
- Expert Opinion
- Public Comments
- Future Research
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
The Four Essentials of Reimbursement

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

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

- Coverage
- Coding
- Payment
- Medical Necessity (Documentation)
The Medicare Reimbursement Process

ICD-9 Codes
Diagnosis/Procedure

DRG Grouper Program

DRG Assignment

Prospective Payment Amount
Hospital Payment:
DRG Assignment Criteria

◆ Clinical Similarity

◆ Resource Consumption
Hospital Payment:
DRG’s for Cerebrovascular Disorders

Major Diagnostic Category 5

Medical Treatment

Intracranial Hemorrhage or Cerebral Infarction

Nonspecific CVA & Precerebral Occlusion w/o Infarct

Nonspecific Cerebrovascular Disorders

Complication and/or Comorbidity

Yes

No

Transient Ischemia

DRG

014

015

016

017

524
Hospital Payment:
Intracranial Hemorrhage or Cerebral Infarct

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
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
DRG Process & Timing

Before Feb / Mar 2005
Early May 2006
May / June 2006
Aug 1, 2006
October 1, 2006

Meet with CMS and Submit Data
Proposed Rule Published
Comment Period
Final Rule Published
Final Rule Becomes Effective
Agenda

10:00 Introductions & Objectives                    S. Liang
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
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3:30 Physician Reimbursement                      P. Marshall
4:15 Next Steps/Close/Adjourn                     S. Liang
Reperfusion Therapies

Clinical benefit

Amount of clinical evidence (NINDS, etc…)

Health Economic Studies/papers regarding improved outcomes
Agenda

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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
Reimbursement Strategy

- Current Health Economics – AIS
- Review Proposed Strategy
- Review Past Discussions – conference call with Dr. Brass
- Discuss/revise current plan
- Develop contingencies
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
OBJECTIVES: ISCHEMIC STROKE AND REPERFUSION REIMBURSEMENT

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

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
CURRENT SITUATION
ISCHEMIC STROKE REIMBURSEMENT*

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

Ischemic stroke

OR/Ix procedure

Yes

No

DRG 14 Intracranial Hemorrhage or Stroke with Infarct

Requires assignment of intracranial hemorrhage diagnosis codes or one of the stroke with infarct diagnosis codes

Base payment = $6,324

DRG 15 Non-Specific CVA & Precerebral Occlusion W/O Infarct

Requires assignment of one of the stroke without infarct principal diagnosis code

Base payment = $4,714

*Medicare reimbursement
CURRENT SITUATION
STROKE PATIENTS BY PRINCIPAL DIAGNOSIS

DRG 14 discharges by principal diagnosis

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

Source: 2003 Medicare MedPAR data
CURRENT SITUATION
STROKE PATIENTS BY PRINCIPAL DIAGNOSIS

The majority of patients have a principal diagnosis of “cerebrovascular accident”

Source: 2003 Medicare MedPAR data
## 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…

<table>
<thead>
<tr>
<th>Of all discharges in DRGs 14 &amp; 15...</th>
<th>N</th>
<th>LOS Mean</th>
<th>Std. Charges Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients receiving a thrombolytic</td>
<td>2,452</td>
<td>6.9</td>
<td>$31,259</td>
</tr>
<tr>
<td>Patients not receiving a thrombolytic</td>
<td>321,757</td>
<td>5.5</td>
<td>$16,213</td>
</tr>
</tbody>
</table>

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

**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
DRG Strategy
Restructure to improve incentives for aggressively treating stroke

Current DRG structure

- Stroke
  - OR/lx procedure
    - Yes
      - DRG 14 Intracranial Hemorrhage or Stroke with Infarct
        - Base payment = $6,324
        - N=241,386
      - No
        - DRG 15 Non-Specific CVA & Precerebral Occlusion W/O Infarct
          - Base payment = $4,714
          - N=82,820

Proposed DRG structure

- Stroke
  - OR/lx procedure
    - Yes
      - DRG 14 Ischemic stroke treatment with a reperfusion agent
        - Base payment = $11,330
        - N=2,452
      - No
        - DRG 15 Hemorrhagic stroke or ischemic stroke w/o a reperfusion agent
          - Base payment = $5,844
          - N=321,757

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

**Issues:**

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

**Mitigating Steps:**
Strategic Alternatives

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
• What are the key messages
• Objectives of the meeting
• What does “Success looks like?”
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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
CMS Presentation
Create Strawman

• 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
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
<table>
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<th>Time</th>
<th>Agenda Item</th>
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Physician Payments
CPT Codes

- American Medical Association
- CPT Editorial Board
- Assigns Physician CPT Codes
Process For New CPT Codes

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
AMA CPT-4 Coding Process

October 2005

February 2006

February 2006 to April 2006

Late April - May 2006

May 2006

January 2007

- Last Date to Submit CPT Application:
- AMA Editorial Panel Meets
- RUC Survey
- AMA Executive Committee Meets
- AMA Submits List of New Codes and Proposed Work Units to CMS
- New CPT Code takes effect.

- Industry
- Physician
- Medical Society
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Meeting Close

Next steps…

Thank you.
J&J Stroke Management Strategic Imperatives


Establish J&J Foundation in Stroke
- Leverage J&J assets for ‘wins’ (MD&D / Pharma)
- Build Pharma basic science competencies
- Market Development - Reimbursement

Mid-term (2007-2010)

Build Stroke Franchise
- Gain market leadership in devices
- Initiate Pharma clinical programs (Phase III)
- Market Development - Physician Education

Long-term (2011 and beyond)

Market Leadership
- Maintain device leadership
- Launch Pharma products
- Market Development - Patient Education

Pursue L&A in priority areas
Treatment Options
Pharmaceutical and Medical Device Opportunities

Current Therapies
• Atrial Fibrillation (AFib)
  ▪ Anticoagulation (Warfarin)
  ▪ Surgical and Ix AFib ablation
  ▪ Left Atrial Appendage Closure

• Aneurysm treatment
  ▪ Coils

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

Prevention
Diagnosis
Treatment
Recovery
Rehabilitation

• Acute diagnosis
  ▪ Stroke differentiator (CT)

• Recanalization
  ▪ Reperfusion agents (tPA)

• Physical therapy

• Aneurysm treatment

• Recanalization
  ▪ Reperfusion agents (ReoPro)

Hemorrhagic Stroke – Novo 7
Major Diagnostic Category 5

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

- OR Procedure
  - Craniotomy Age >17 (Includes Glues and Coils)
  - Intracranial Vascular Procedure w/ PDX Hemorrhage

Complication and/or Comorbidity

DRG

- Yes → 1
- No → 2

528
## Craniotomy Procedures

<table>
<thead>
<tr>
<th>DRG</th>
<th>Description</th>
<th>Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>Craniotomy Age &gt;17 w/ cc</td>
<td>$16,600</td>
</tr>
<tr>
<td>002</td>
<td>Craniotomy Age &gt;17 wo/ cc</td>
<td>$9,700</td>
</tr>
<tr>
<td>528</td>
<td>Intracranial Vascular Procedure w/ PDX Hemorrhage</td>
<td>$34,000</td>
</tr>
</tbody>
</table>
### Nonspecific Cerebrovascular Disorder w/ CC

#### Hospital Coding

#### FY 2005

<table>
<thead>
<tr>
<th>Principal Diagnosis:</th>
<th>Principal Procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>437.0 Cerebral Atherosclerosis:</td>
<td>99.10 Infusion of thrombolytic +/-.</td>
</tr>
<tr>
<td></td>
<td>99.20 Infusion of platelet inhibitor +/-.</td>
</tr>
<tr>
<td></td>
<td>88.41 Angio of Cerebral Artery</td>
</tr>
</tbody>
</table>

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

FY 2005

DRG 524 $3,700
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
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 +/- 88.41 Angio of Cerebral Artery

DRG 524 $3,700
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Mission
Improving outcomes through the prevention and treatment of stroke

Vision
Leading the global revolution against stroke
The J&J Credo

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, newfacilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.
Stroke Competitive Landscape: Why Is J&J Equipped to Win in Stroke?

“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**
- Centocor
- McNeil
- Johnson & Johnson

**Devices**
- PGSM
- Biosense Webster
- Cordis
- CardioVations
- Codman

**Diagnostics**
- Ortho-Clinical Diagnostics

**Other**
- J&J
- COSAT
- NDC
J&J Stroke Management Strategy Development Process

- **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**
J&J Stroke Management Strategic Imperatives

**Near-term (2004-2006)**

- **Establish J&J Foundation in Stroke**
  - Leverage J&J assets for ‘wins’ (MD&D / Pharma)
  - Build Pharma basic science competencies
  - Market Development - Reimbursement

**Mid-term (2007-2010)**

- **Build Stroke Franchise**
  - Gain market leadership in devices
  - Initiate Pharma clinical programs (Phase III)
  - Market Development - Physician Education

**Long-term (2011 and beyond)**

- **Market Leadership**
  - Maintain device leadership
  - Launch Pharma products
  - Market Development - Patient Education

---

**Pursue L&A in priority areas**
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CMS Decision Making Process

- Criteria/process for change
- Decision Makers
- Timelines