

Reimbursement for Novel Technology: Clinical Data Implications for Coverage Decisions

Gretchen Benko Mruk

Commercial Marketing, Concentric Medical, Inc.

Overview:

- Evidence is King
 - Clinical data has lasting implications for reimbursement and coverage policies
- Plan ahead / Plan accordingly
 - Anticipate the clinical story for physicians, societies and payors

Stroke: A Healthcare Priority

795,000 new or recurrent strokes annually – 87% Ischemic

Up to 50% of ischemic strokes are large vessel / severe strokes

Third leading cause of death, leading cause of disability

2010 estimated cost of stroke: \$73.7 billion

**Over 90% of patients may
not receive acute
intervention**

Sources:

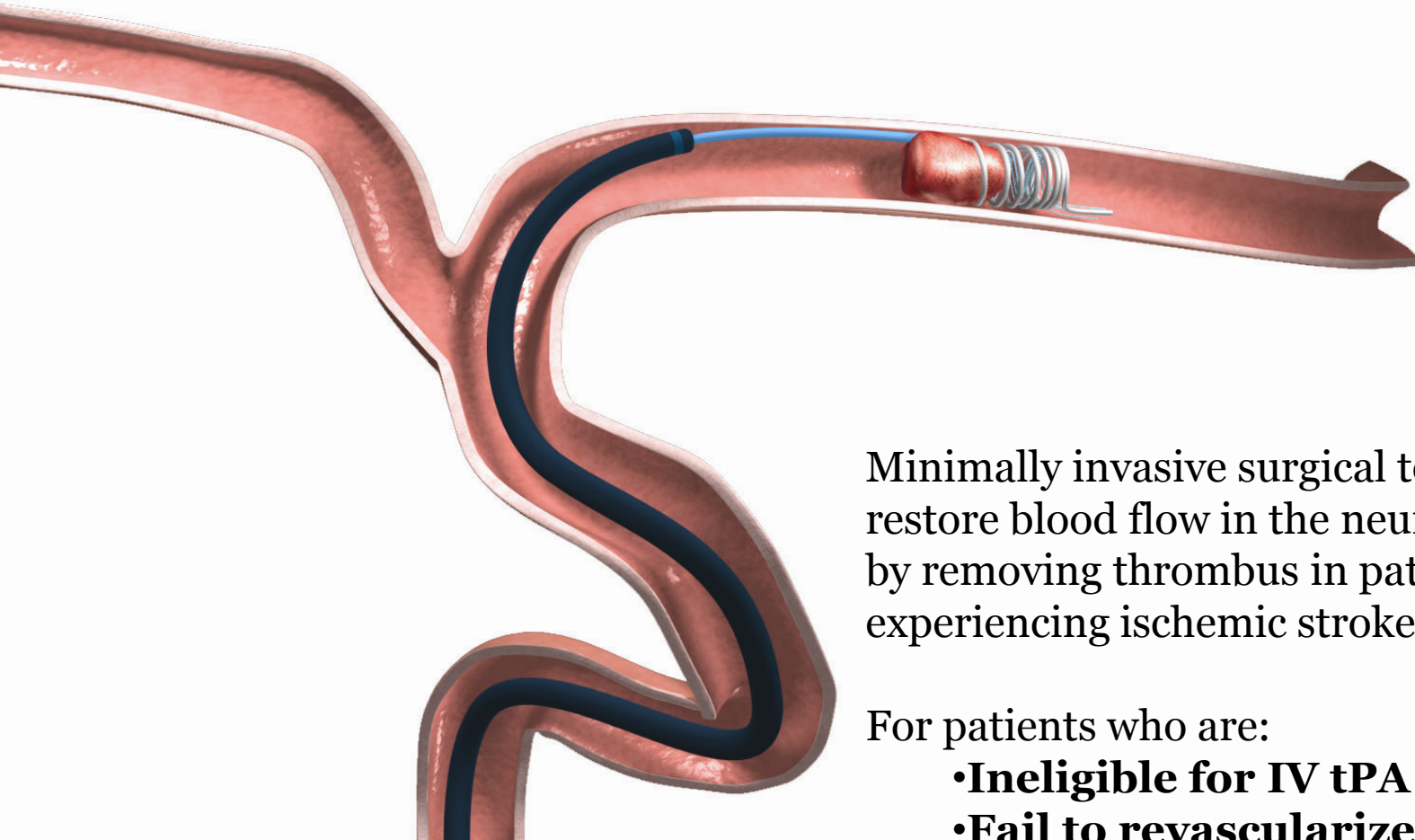
Heart Disease and Stroke Statistics—2009
American Hospital Directory, Online Database

The Face of Stroke

Payer Mix
59% Medicare
41% non-Medicare



Mechanical Embolectomy with the Merci Retriever®




Minimally invasive surgical technique to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke.

For patients who are:

- **Ineligible for IV tPA or who**
- **Fail to revascularize with IV tPA**

Cleared by the FDA in 2004

Mechanical Embolectomy Provides an Option for Stroke Patients



Time from Symptom Onset	0-3 hours	0-4.5 hours	0-6 hours	0-8+ hours
IV t-PA ¹	—————→		
IA t-PA ²	—————	—————	—————→	
Merci ³	—————	—————	—————	—————→

¹FDA approval is for 0-3 hours only


²Not an FDA-approved indication

³Approved for use in the 0-3 hour window for patients who are ineligible for IV tPA or who fail to respond to IV tPA ; Indication for use does not have a time window upper limit

Commercial Payor Non-Coverage

- Non-coverage policy: mechanical embolectomy is **investigational** and **not medically necessary**
- Two prospective, multi-center single arm trials with over 300 patients in total
 - MERCI
 - Ineligible for IV tPA
 - Multi MERCI
 - Ineligible for or who fail IV tPA

Table 1. Applying Classification of Recommendations and Level of Evidence

		SIZE OF TREATMENT EFFECT 			
		CLASS I <i>Benefit >>> Risk</i> Procedure/Treatment SHOULD be performed/administered	CLASS IIa <i>Benefit >> Risk</i> <i>Additional studies with focused objectives needed</i> IT IS REASONABLE to perform procedure/administer treatment	CLASS IIb <i>Benefit ≥ Risk</i> <i>Additional studies with broad objectives needed; additional registry data would be helpful</i> Procedure/Treatment MAY BE CONSIDERED	CLASS III <i>Risk ≥ Benefit</i> Procedure/Treatment should NOT be performed/administered SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL
ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
	LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
	LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care

Suggested phrases for writing recommendations[†]

should
is recommended
is indicated
is useful/effective/beneficial

is reasonable
can be useful/effective/beneficial
is probably recommended
or indicated

may/might be considered
may/might be reasonable
usefulness/effectiveness is unknown/unclear/uncertain
or not well established

is not recommended
is not indicated
should not
is not useful/effective/beneficial
may be harmful

Randomized Data - in perspective

- Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomized controlled trials.



Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials

Smith, G. Pell, J. Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *British Medical Journal* 2003; Dec (327): 1459-1461

- “We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.”



Affecting a Non-Coverage Policy

- Monitor the reimbursement landscape
- KOLs and physician societies are key
 - Letters and discussions with medical director
 - Consensus Statements
- Customer involvement
 - Physician letters
 - Patient activists
- Seek new in-roads
 - Patient advocacy groups, lobbyists, public personality, hospital groups
- Engage smaller payors first
- Utilize the appeal process

Clinical Plan should include Reimbursement Strategy

Planning a Clinical Strategy

- Understand the levels of evidence and anticipate what might be required
 - **Device vs. Drug Primary Endpoints:**
 - Devices studies - effectiveness , pharmaceutical studies - clinical outcomes
 - What are the current guidelines?
- Work with the Clinical Team
 - Pro-actively engage in protocol development. If your therapy may be used by younger patient population, power study to evaluate younger, non-Medicare-age patients
 - What other technologies/treatment options exist?
 - What will the standard of care be in three years?

Key Takeaways

- Evidence is King
 - Work with clinical dept on trial design and endpoints
 - Move to evaluate clinical outcome
 - Consider Randomized data vs. single arm prospective data
- Bringing data to the discussion with payor
 - Review Literature - continually identify key studies as they are published
 - Review bibliography of coverage decision and provide summaries of missing data and full articles if able
 - Clarify for payors key trial differences and proposed patient populations
 - Utilize KOLs and societies
- Have a plan and be ready to implement

Questions

