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Subject: Anthem Policy Mechanical Embolectomy for Treatment of Acute Stroke

Dear Dr. Whitney,

On behalf of the American Association of Neurological Surgeons (AANS), the American Society of Neuroradiology, the Congress of Neurological Surgeons (CNS), the Society of NeuroInterventional Surgery, and the Society of Vascular and Interventional Neurologists, we would like to thank WellPoint and Anthem for the opportunity to comment on the Anthem medical policy SURG.00098 (Effective Date: 4/11/2012) on the subject of "Mechanical Embolectomy for Treatment of Acute Stroke." We appreciate the efforts of your team in developing a review of the published literature reporting on the use of mechanical embolectomy in the treatment of acute stroke, but **disagree** that such intervention is investigational and not medically necessary.

We believe that for acute ischemic stroke, mechanical embolectomy is a medically necessary option in appropriate in patients with medical indications as determined by their treating physician. Our assessment of the literature would indicate that mechanical embolectomy is an appropriate option in patients:

- Presenting outside the 3-4.5 hour window for intravenous tissue plasminogen activator (IV tPA).
- Patients in whom IV tPA was not effective at recanalizing the vessel.
- Patients who have calcified clots or calcified deposits.
- Patients who have large vessel occlusion of their internal carotid artery (ICA) or basilar artery (BA)

We are concerned that the medical policy compounds the omission of the grave natural history and the state of the literature. Specifically, the policy states:

- "Overall, controversy exists regarding the clinical implications of the MERCI study (Becker, 2005; Davis, 2006; Saver, 2006; Weschler, 2006). A number of commentators feel that recanalization rates represent an intermediate outcome, and that data on clinical outcomes is needed. Additionally comparison to historical controls is not adequate to validate the safety and effectiveness of mechanical embolectomy; randomized, controlled trials are needed."

The devices utilized for mechanical embolectomy have been approved by the Food and Drug Administration (FDA). The study designs in our field reflect the internal control offered by stroke pathophysiology. In the absence of meaningful intervention, pre-procedural National Institutes of Health Stroke Scale (NIHSS) offers a preview of long-term functional status were the stroke to proceed to completion. Moreover, once the seminal connection between technical success and clinical outcomes was proven, device trials began to emphasize the technical success and efficiency of flow restoration for occlusions at various levels of the cerebrovasculature. We disagree with the implication that the efficiency of neurovascular thrombectomy in practice matches established efficacy in the literature, which is a non-trivial policy point.

In addition, IV tPA and neurovascular thrombectomy do not represent mutually exclusive therapies. Thrombolytic reperfusion therapy (IV rTPA is viable in less than five percent of patients with acute stroke (AHRQ Draft Technical Brief on Neurothrombectomy Devices for Treatment of Acute Ischemic Stroke, 2010) and the natural history of stroke represents a more reasonable baseline for the assessment of neurothrombectomy devices. It is clear that long-term dependency or mortality awaited these patients who did not respond to IV tPA in the absence of meaningful intervention. The stark and costly reality of moribund dependence is the true alternative to neurothrombectomy devices; these gravely stricken patients are the population of interest. The difficulty in comparing studies for devices is that most include patients that have presented between 0 - 8 hours, in comparison to studies looking at intraarterial (IA) tPA or combined IV and IA tPA which only included patients within a 3 or 6 hour window, reducing the average number of patients that have a benefit.

Many studies including the Interventional Management of Stroke (IMS II) Trial determined that recanalization of cranial vessels is important for treatment of stroke:

- The faster a vessel is opened the better the patient outcome.
- tPA cannot always be used or is known to not be effective in some instances
- In patients with calcified plaques or very organized clot
- Clot obstructing large vessels like the ICA
- People with contraindications to tPA

In many instances, if IV and IA tPA fail to re-canalize a vessel, then the patient typically is treated with mechanical embolectomy within an 8 hour window. IA and IV tPA studies continue to presume the improved outcome is due to recanalization, and one would assume that patients who do poorly either had a hemorrhage or failed to have recanalization. Unfortunately, there has never been a study that looks at the patients treated with IA or IV therapy that failed and then randomized those patients to a mechanical device. But based on the best available evidence currently, it would seem that improved outcomes are related to recanalization within the 8 hour window.

Conclusion

We appreciate the opportunity to review and comment on the Anthem medical policy SURG.00098 (Effective Date: 4/11/2012) on the subject of “Mechanical Embolectomy for Treatment of Acute Stroke”. Thank you for considering our comments. We recognize that mechanical embolectomy is a costly technology and is not appropriate for all patients with acute stroke. However, we believe that for acute

ischemic stroke, mechanical embolectomy may be a beneficial and necessary option for many patients and should not be considered "investigational and not medically necessary". After review of the current literature, the AANS and CNS believe mechanical embolectomy remains an important treatment alternative for clinically appropriate cases, as chosen by treating physicians.

Again, thank you for this opportunity to comment and we hope you will reconsider your medical policy regarding mechanical embolectomy in acute stroke. If you have any questions, please feel free to contact Joseph Cheng, MD (joseph.cheng@vanderbilt.edu), Committee for Payor and Policy Responses, or Catherine Hill, Senior Manager, Regulatory Affair AANS/CNS (chill@neurosurgery.org).

Sincerely,

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