September 7, 2006

Dear Dr. McClellan,

I am writing to respond to the current inquiry into Medicare/Medicaid coverage of the Wingspan Stent Gateway system. (CAG 00085122). I am the Nurse Practitioner for the Neuroradiology team here at the University of Maryland Medical System In Baltimore. We work very closely with the Brain Attack Team also established here.

Currently, the only treatment option available to patients with >50% symptomatic intracranial stenosis, despite maximal medical therapy, is angioplasty and stenting. The Wingspan/Gateway system has provided an FDA approved mechanism for angioplasty and stenting in the intracranial vasculature. As you know, off-label use of cardiac stents had been used prior with marginal if not deleterious events.

These patients often cannot afford to “promise” to take on the expense of this system should they require it. Further, it is frustrating to both sides to offer only angioplasty simply because an insurer refuses to pay for a therapy FDA approved and available. These patients are screened carefully for compliance to medical regimen and seen often for visits. Should non-coverage occur, there will no doubt be unacceptable, unnecessary loss of life.

I urge you to strongly consider fully covering this essential interventional therapy helping us to wage the war on stroke and its debilitating implications.

Sincerely,

Deborah L. Schofield, M.S., CRNP

22 SOUTH GREENE STREET
BALTIMORE, MARYLAND 21201
NEURORADIOLOGY

Commenter: William O. Bank, MD
Title: Chief, Neuro Interventional Service
Organization: Washington Hospital Center
Date: 09/06/2006

Dear Dr. McClellan:

This letter is in response to the request from the Centers for Medicare and Medicaid Services (CMS) for comments on the national Medicare coverage for intracranial stenting and angioplasty (CAG – 00085R2).

As Chief of the Neuro Interventional Service at the Washington Hospital Center in Washington, DC, (our nation's 20th largest hospital), I evaluate and treat a large number of patients with cerebrovascular disease and stroke. Our program is an integral part of the Stroke Team of the National Institutes of Health (NIH).

Many of the patients that I see have symptoms caused by intracranial atherosclerotic stenosis and their symptoms have not been relieved by optimal medical therapy with antiplatelet and/or anticoagulant drugs. Angioplasty (with or without stenting) of their stenotic lesions represents the only viable treatment option for these patients.

Until recently the only way to perform such treatment was to use balloons and stents designed to treat stenoses of the coronary arteries (off-label). Reaching the intracranial stenoses with devices that are not designed to reach the brain has been the limiting factor: the stiffer coronary systems, although they are the correct size, cannot be navigated around the necessary loops and bends to reach the brain arteries. This has significantly increased the morbidity and mortality of this procedure.

We now have a combination of devices designed to reach the target area in the brain and treat these lesions: the Gateway balloon and Wingspan stent have significantly improved our ability to reach and treat intracranial stenoses.

The current non-coverage policy, however, represents a severe financial burden for the majority of my patients and for my hospital system. Presenting the patient and their family with an Advanced Beneficiary Notice detailing the high cost of an uncovered treatment is a very unpleasant experience for me and for many of my colleagues, an experience that is becoming all too frequent. For many patients and their families, the decision to proceed with a life-saving but uncovered treatment creates a financial crisis. Most patients and their families become confused and angry about the conflicting advice from me as a physician recommending angioplasty and stenting as the best treatment option for their problem using a device that has been approved for marketing for their rare condition by the FDA, while their insurance companies claim that such treatment is "experimental."

I urge CMS to issue an expeditious coverage decision that includes:
1. Coverage for intracranial angioplasty (with or without stenting) for patients with symptomatic >50% intracranial arterial stenosis who have been refractory to medical therapy.
2. Coverage for intracranial angioplasty and stenting within the context of Category B investigational device exemption (IDE) trials.
I request your careful consideration of Medicare coverage and reimbursement for these life-saving treatment options, of which current patient access is significantly impaired by the longstanding national non-coverage policy (Manual Section Number, 20.7 Percutaneous Transluminal Angioplasty).

You have received other comments detailing the Science involved in the development and use of intracranial angioplasty and stenting. Do not neglect the focus of the many newspaper articles and television coverage that discuss the importance of rapid response to stroke symptoms and the need to develop "Stroke Teams" in all regional hospitals. Patients and their families become angry when they respond in time only to discover that the treatment they need is not covered.

I request that CMS provide access to this life-saving technology for patients with limited treatment options. I thank you for your consideration of this critical health policy issue.

Sincerely,

William O Bank, MD
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It would be quite unwise to deny payments for the only treatment that has been shown to improve outcomes in patients with significant symptomatic intracranial stenoses. I certainly wouldn't be happy if my family member was denied access to this treatment, and I'm certain that you wouldn't be happy either. In my opinion it would be immoral and unethical to withhold payment for these services, although I'm not certain that that is a significant concern of yours.
sincerely, scott agran, md

scottagran@yahoo.com