

The Honorable Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of The Vascular Institute of St. Joseph Hospital, Orange, California, I kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects my hospital's financial ability to provide this lifesaving treatment to critically ill patients.

Below, I provide clinical background and my institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.^{1[1]} Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2[2],3[3],4[4]} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.^{5[5]} Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration

approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.^{6[6]} Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.^{7[7]}

At my institution, we treat large numbers of patients with vascular disease. We have experienced an increasing number of patients whose primary disorder is an intracranial stenosis refractory to medical management.

Furthermore, at the Vascular Institute, we treat many patients with acute subarachnoid hemorrhage, a number of who require intracranial angioplasty for treatment of refractory post-bleed vasospasm. Although, both endovascular coiling and open surgical clipping of intracranial aneurysms are covered services for the treatment of intracranial aneurysms, post-bleed vasospasm can be just as deadly as a new bleed from the aneurysm. In some patients, angioplasty of the vasospasm is the only effective and durable therapy that we have to offer. It is not reasonable to leave this therapy uncovered.

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.^{8[8]} Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.
- 3) National Medicare coverage for intracranial angioplasty in the setting of refractory intracranial vasospasm.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Howard L. Dorne, M.D.

[1] American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

[2] Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563.

[3] Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

[4] The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke. Results of an international randomized trial. *New England Journal of Medicine*. 1985; 313:1191-1200.

[5] Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

[6] Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

[7] Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

[8] Higashida, *et al*. Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

I am writing in support of the attempts to obtain HDE approval for intracranial angioplasty & stenting. I have been performing these procedures since 1998, and significant number of these patients had recurrent symptoms on medical therapy, and did well after the complex procedure. Data in support of these procedures is gradually emerging, and my experience has been that often these patients have few options for revascularization of very severely diseased vessels with potential for recurrent strokes. I am hoping that industry will invest in developing technology suited for the intracranial vasculature, as the current technical limitations and challenges can be daunting for most operators, and are clearly not adequate to meet the needs of this challenging vascular bed.

Vijay Misra, MD
Associate Professor of Medicine
Division of Cardiology
Director of Cardiac Catheterization Laboratory
University of Alabama at Birmingham
Birmingham, AL 35294

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Re: NCA - Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

I am one of the Neurointerventionalists in Houston Texas. We at UT Houston Health Science Center handle the biggest stroke patient population in Texas. In my encounter with numerous patients with acute and chronic stroke, I know that there are numerous situations where the device(s) could have been and can be highly instrumental in optimizing the circulatory perfusion of the affected functional and eloquent areas of the brain. The morbidity and mortality in the cases that become refractory to conservative medical treatment, along with the inherent INCREMENTAL cost of more complex prolonged hospitalization and follow-up care could probably be minimized with the availability and encouraged availability and use of the device (s).

I would personally recommend favorable consideration to the Medicare reimbursement of the cost of the device(s), the first of its kind to be approved by the F.D.A. for Human use.

Respectfully yours,

Edwin D. Cacayorin, M.D.
Professor and Chief
Diagnostic and Interventional Neuroradiology
UT Houston Health Science Center
6431 Fannin Street, MSB 2.100
Houston, Texas 77030

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Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Medical College of Wisconsin and Froedtert Hospital we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.^[1] Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{[2],[3],[4]} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

Patient was admitted to the hospital with 4-5 month history of dizziness and falls. Patient has a history of hypertension, hyperlipidemia and 40- pack –year smoking history quitting 20 years ago. CTA revealed tortuous cerebral arteries and basilar artery stenosis. The patient was scheduled for a Wingspan stent placement with excellent results. The Wingspan stent is very flexible, easily navigated through cerebral arteries and carries less risk during the procedure compared to earlier stainless steel stents. This is one example of 10 Wingspan cases performed since IRB approval December 15, 2005 and several cases pending per patient request do to reimbursement issues.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.[5] Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.[6] Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.[7]

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

- **The Medical College of Wisconsin and Froedtert Hospital Interventional Neurology Department services the greater Metropolitan Milwaukee area. Froedtert Hospital and the Medical College of Wisconsin is committed to stroke patient care and provides the only adult level 1 trauma center in eastern Wisconsin and a 24 hour on call stroke team. Froedtert and the Medical College of Wisconsin is at the forefront of heart disease, stroke and brain injury research. Froedtert has a 430 patient bed capacity serving on average 482 stroke cases a year with an average 62% of these patients being Medicare patients.**
- **FDA-approved device allow our institution to provide quality state of the art technology to our patients.**
- **Non-coverage policy will impede the hospital's ability to provide this treatment to patients. Currently 63% of stroke patients have Medicare coverage.**

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American

Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.[8] Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Dr. Osama O. Zaidat , MD
Associate Professor
Director, Neurointerventional Program

^[1] American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

^[2] Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563.

^[3] Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

^[4] The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke. Results of an international randomized trial. *New England Journal of Medicine*. 1985; 313:1191-1200.

^[5] Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

^[6] Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

^[7] Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

^[8] Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

Saturday, March 11, 2006 8:08 AM

Dear Ms. McClain & dr. Chin,

I am a neurosurgeon in Saint Louis Missouri. I provide all the endovascular services for my hospital. Over the past 3 years I have had to send at least 8 patients to one of the academic centers in town for intracranial bypass procedures do to our inability to provide intracranial stenting for cerebrovascular atherosclerosis. I urge CMS to issue a positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with stenting and percutaneous transuminal angioplasty (PTA) balloon catheters. Stroke is a well known leading cause of death and disability in the United States and this is often the case for patients who have intracranial carotid atherosclerotic disease. Studies clearly support Medicare coverage of PTA with or without stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who present with appropriate symptoms. Under the current non-coverage policy, access to effective care is restricted for many patients. This results in needless suffering from preventable strokes. CMS should therefore make this lifesaving technology available to Medicare patients. Thank you for considering my comments.

Sincerely,

Thomas Forget MD
St. John's Mercy Medical Center
St Louis, Missouri

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

On behalf of The University of Texas/Southwestern Medical Center, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan* Stent System with Gateway* PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States. Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke. If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy. Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. We have treated approximately 50 patients at our institution as a last resort after all medical therapy has failed. We unfortunately only have had coronary technology (stents and balloons) available to us, and the complication rates of these stiff devices in the tortuous intracranial vasculature are high, approximately 15%.

On August 3, 2005, the Food and Drug Administration approved the Wingspan* Stent System with Gateway* PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions. Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement. As a significant percentage of patients, perhaps the majority, are in the Medicare population, failure to receive reimbursement for these devices from Medicare denies the benefit to the very population this system was designed for.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for

marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Robert E. Replogle M.D
Assistant Professor of Radiology and Neurosurgery
UT Southwestern Medical Center

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA ? Intracranial Stenting and Angioplasty (CAG-00085R2)

Dr. McClellan:

Intracranial atherosclerotic disease kills and cripples thousands of people a year in this country, and there is currently no approved treatment, barring antiplatelet medications or anticoagulation, both of which have been recently shown to have miserable preventive effect in the recent WASID trial. We need tools to treat this disease more aggressively given the poor natural history, and those tools include intracranial angioplasty and stenting. Please do the right thing, reverse the CMS non-coverage policy with regard to these procedures, and help allow us to provide superior treatment to our patients. Thank you for your consideration.

Sincerely,

Jonathan Hartman, M.D.
Adjunct Assistant Professor of Radiology, UC Davis School of Medicine
Neurointerventional Radiology/Endovascular Neurosurgery
Department of Neurosurgery
Kaiser Permanente Medical Center
2025 Morse Avenue, Room 3717
Sacramento, CA 95825-2115

From: Brant-Zawadzki, Michael

Subject: "NCA for Intracranial Stenting and Angioplasty (CAG-00085R2)". **

To whom it may concern:

As an interventional neuroradiologist, I urge you to consider coverage for intracranial stenting/angioplasty in patients with documented occlusive disease of the major intracranial arteries, who have failed anti-platelet/coagulant therapy and exhibit recurrent symptoms in the territory served. This relatively small number of patients has a very high risk for devastating stroke, and has no other therapeutic options in this setting.....

*Dr. Michael Brant-Zawadzki MD FACR
Medical Director, Radiology; Hoag Memorial Hospital
Adjunct professor of Radiology, Stanford University*

March 10, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
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Washington, DC 20201

Re: NCA-Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

I am writing this letter on behalf of Our Lady of Lourdes Medical Center in Lafayette, Louisiana. I am requesting CMS issue a positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan Stent System with Gateway Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter.

The Current national non-coverage policy directly affects a hospital's financial ability to provide this life-saving treatment to critically ill patients. Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. It requires an Interventional Radiologist, nursing personnel, anesthesiologists, special procedure technologists and circulating personnel. Economically, it is not feasible for any hospital to allow these procedures to be performed without reimbursement.

Stroke is the third leading cause of death in the US. It is the leading cause of long-term disability. Most stroke patients are treated with medical therapy but in some cases this therapy is ineffective and patients are left with a high risk for another stroke in the year after their original stroke. There are limited treatment options if medical therapy fails and a stroke victim's quality of life is compromised.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade Stenosis who fail medical therapy. In the past, Coronary devices were the only available devices for treatment. They were not designed for nor indicated for intracranial use. In 2005, the FDA approved the Wingspan Stent System with Gateway PTA Balloon Catheter under a Humanitarian Device Exemption. It is the first stent specifically designed for the intracranial vasculature. Studies showed the majority of patients treated with this device were free of strokes related to their previously treated lesions.

To continue to provide this life saving treatment option, I feel CMS should act quickly to reverse its non-coverage policy and ask for national Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy. This should be concurrent with use of a device approved for marketing by the FDA.

Thank you for your time and attention to this extremely important health policy initiative.

Sincerely,
Daniel C. Dunlap, MD

From: Phillip Purdy

Subject: Wingspan stent coverage for cerebral atherosclerosis

Dear Ms. McClain:

I am writing in support of approval for coverage for intracranial stenting with angioplasty with a Humanitarian Device Exemption for the Wingspan Stent System with Gateway PTA Balloon Catheter, with the indication of improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with >50% stenosis that are acceptable to the system. It is well-known that in symptomatic cerebral artery stenosis, there is a high risk of stroke in the absence of improvement of flow, just as is the case with symptomatic carotid artery stenosis. There are no proven surgical alternatives, and even in patients with anatomy favorable to cerebral artery bypass, the complication rate from the bypass operation has been proven to be high due to subsequent occlusion at the level of the stenosis. Endarterectomy of the intracranial vessels is fraught with problems where it can be done and it cannot be done in the basilar artery, a frequent site of symptomatic intracranial atherosclerosis.

Since atherosclerosis is a process that progresses with age, the Medicare patient population is especially at-risk, and hence represents a patient population that would especially stand to benefit from approval of intracranial stenting when medical treatment has failed. Even medical treatment (anticoagulation with warfarin) is fraught with risk in this population.

I would therefore strongly support approval of this option for the patient population cited above.

Thank you very much.

Phillip Purdy, M.D.
Director of Neuroradiology
UT Southwestern Medical Center
Dallas, Texas



March 10, 2006

Mark McClellan, MD, PhD
CMS Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mailstop C5-25-25
Baltimore, MD 21244-1850

Re: NCA Tracking Sheet – Intracranial Stenting and Angioplasty (CAG- 00085R2)

Dear Dr. McClellan:

The American Society of Interventional and Therapeutic Neuroradiology (ASITN) appreciates the opportunity to provide input to the Centers for Medicare and Medicaid Services' (CMS') request for comments on the national Medicare coverage for intracranial stenting and angioplasty (CAG – 00085R2).

On behalf of our professional society, we urge CMS to issue an expeditious coverage decision, which includes the following:

1. Positive coverage for intracranial angioplasty and/or stenting for patients with symptomatic $\geq 50\%$ intracranial arterial stenosis who are refractory to medical therapy.
2. Coverage for intracranial angioplasty and stenting within the context of Category B investigational device exemption (IDE) trials.

We 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). Additional perspective on our organization's position and clinical experience with interventions for this disease is provided below.

Background on ASITN

The American Society of Interventional and Therapeutic Neuroradiology (ASITN) consists of more than 500 interventional neuroradiologists, interventional neurologists, and endovascular neurosurgeons, who are dedicated to neurointerventional surgery. Our society is committed to promoting excellence in patient care, education, and research, and also to promote health care policy in support of such initiatives.

Intracranial Atherosclerotic Disease

Intracranial atherosclerotic disease (ICAD) is the narrowing and blockage of intracranial vessels, which results in reduced blood flow to the brain. ICAD is recognized as a significant risk factor

for stroke, accounting for up to 10% of all ischemic strokes.¹ The majority of these patients are treated with medical therapy. However, there is a **small population of patients who, despite medical therapy, remain at high risk for stroke.**^{2,3,4} Two recent publications from the Warfarin versus Aspirin for Symptomatic Intracranial Disease (WASID) trial, (a randomized trial comparing warfarin and aspirin for preventing stroke and vascular death in 569 patients with ICAD), showed that symptomatic intracranial stenosis of greater than or equal to 50% carries a high risk of stroke, whether treated by antiplatelet or anticoagulant medications. For patients who presented with a non-disabling stroke secondary to an intracranial stenosis of $\geq 70\%$, 23% suffered a same territory within one year despite best medical management.

ICAD Treatment Options in Symptomatic Patients

Currently, patients with symptomatic intracranial atherosclerotic arterial stenosis have limited treatment options. Medical therapy has been proven ineffective at stroke prevention for a small subset of such patients. Based on data from a global, randomized controlled study, extracranial to intracranial arterial bypass surgery was also found to be ineffective.⁴

Endovascular intracranial angioplasty and/or stenting, has reported compelling clinical results in the past decade.^{5,6} Most recently, the ASITN in conjunction with the Society of Interventional Radiology (SIR) and the American Society of Neuroradiology (ASNR) conducted a thorough review of the medical literature and released a joint position statement which supports: **intracranial stenting and angioplasty for symptomatic patients with a $\geq 50\%$ intracranial stenosis.** The position statement was concurrently published in the October 2005 issues of *The Journal of Vascular & Interventional Radiology* and *The American Journal of Neuroradiology*.^{7,8}

Case series reports of balloon angioplasty and stenting procedures have demonstrated technical success rates in the published literature of greater than 90 percent. The existing clinical evidence shows clear benefit of endovascular treatment in symptomatic patients with greater than or equal to 50% intracranial stenosis.

CMS had formulated the original national non-coverage policy for the ICAD patient population in 1994. The ASITN agrees that, at that time, the risk of treatment using the available technology

¹ American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

² Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563.

³ Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

⁴ The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke. Results of an international randomized trial. *New England Journal of Medicine*. 1985; 313:1191-1200.

⁵ Stenting of Symptomatic Atherosclerotic Lesions in the Vertebral or Intracranial Arteries (SSYLVA): study results. *Stroke*. 2004;35:1388-92.

⁶ Jiang WJ, Wang YJ, Du B, Wang SX, Wang GH, Jin M, Dai JP. Stenting of symptomatic M1 stenosis of middle cerebral artery: an initial experience of 40 patients. *Stroke*. 2004;35:1375-80.

⁷ Higashida RT, Meyers, PM, Connors JJ, Sacks D, Strother CM, Barr JD, Wojak JC Duckwiler, GR. Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: A Position Statement of the American Society of Interventional & Therapeutic Neuroradiology, Society of Interventional Radiology and the American Society of Neuroradiology. *J Vasc Interv Radiol* 2005 16:1281-1285.

⁸ Higashida RT, Meyers, PM, Connors JJ, Sacks D, Strother CM, Barr JD, Wojak JC Duckwiler, GR. Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: A Position Statement of the American Society of Interventional & Therapeutic Neuroradiology, Society of Interventional Radiology and the American Society of Neuroradiology. *AJNR Am J Neuroradiol* 2005 26:2323-2327.

and the relative lack of understanding regarding the natural history of ICAD supported the national non-coverage policy. However, there have been significant advances in medical knowledge, technology and techniques in the last ten years. The dismal natural history of ICAD has now been documented. These changes have rendered the existing non-coverage policy inappropriate.

Further, in August 2005, the Food and Drug Administration (FDA) approved the Wingspan Stent System with Gateway PTA Balloon catheter via Humanitarian Device Exemption (HDE). The HDE approval process is a streamlined FDA approval process that is meant to improve patient access to treatments for rare and orphan diseases based on the requirement of demonstrating safety and probable benefit of the technology. The FDA HDE approval process is supported by the fact that it otherwise would be statistically unfeasible to amass large clinical studies to prove clinical effectiveness whereas approval based on probable benefit is substantiated given that the HDE population faces no other treatment alternatives. The Wingspan Stent System represents a promising endovascular therapy in the management of ICAD in medically refractory patients with $\geq 50\%$ stenosis. Data from the Wingspan HDE clinical study are encouraging and clearly support its use in this underserved population. The Wingspan study's 12 month clinical trial results, recently presented by the study's principal investigator on February 17th at the International Stroke Conference indicate that **90% of patients participating in the study were free of strokes related to their treated lesions at one-year post-procedure.**⁹ The majority of patients treated in the Wingspan study had an arterial stenosis of $> 70\%$ and had presented with stroke. In comparison, the one-year ipsilateral stroke rate among similar patients treated by medical therapy in WASID was 2.3 times as high.

Prior to the approval of the Wingspan stent system, the FDA had granted an HDE for the Guidant NeuroLink intracranial stent system in 2002. Guidant elected to discontinue manufacturing and selling this stent within the next year. Although we do not have access to official Guidant sources for documentation, we believe this stent system was withdrawn from the market because the lack of reimbursement for intracranial stenting made the project impossible to justify from a financial perspective. As we were made aware that the Wingspan and other stent systems were under development. ASITN, assisted by a coalition of other medical societies, developed the recently approved CPT codes necessary to ensure that intracranial angioplasty and/or stenting will become available treatment options for certain patients with ICAD.

The results of the Wingspan clinical study and numerous publications on intracranial angioplasty and stenting show that intracranial angioplasty with or without stenting is a reasonable and necessary approach in the medically unresponsive ICAD population with $\geq 50\%$ stenosis.

Clinical Evidence Supports Medicare Coverage

Due to the lack of other viable treatment alternatives, the significant risks of stroke and death associated with not providing treatment, and the proven benefit of angioplasty and/or stenting in this patient population, the ASITN asks that the Centers for Medicare & Medicaid Services (CMS) remove the economic hardship on patients and hospitals by providing the following:

⁹ Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

1) An accelerated reconsideration of the current non-coverage policy with a positive coverage decision for intracranial angioplasty and/or stenting for patients with symptomatic $\geq 50\%$ intracranial arterial stenosis who are refractory to medical therapy. .

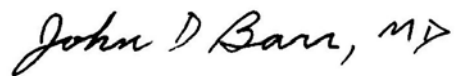
An expedited positive coverage decision is critical to address the unmet medical need of this underserved patient population that could benefit from intracranial angioplasty and stenting. WASID and other data clearly support that such patients are at high risk of stroke when treated with the best available medical therapy. **As many as half of ICAD patients not responding to medication have a treatment failure within a median time of 36 days, with half of these therapeutic failures experiencing a major stroke or death within this time frame.**¹⁰

Therefore, it is crucial that CMS provide access to intracranial atherosclerotic angioplasty and stenting through coverage as soon as possible.

2) Coverage for intracranial angioplasty and stenting within the context of Category B investigational device exemption (IDE) trials. Providing coverage for these procedures and related services within future IDE trials would support the collection of robust clinical evidence regarding the effectiveness of this procedure in other patient populations for the prevention of stroke.

The ASITN requests that CMS provide access to patients with limited treatment options to this life-saving technology as soon as possible. We thank you for your consideration of this critical health policy issue.

Sincerely,

A handwritten signature in black ink that reads "John D. Barr, MD". The signature is written in a cursive, slightly slanted style.

John D. Barr, MD
President

¹⁰ Thijs VN, Albers GW. Symptomatic intracranial atherosclerosis: outcome of patients who fail antithrombotic therapy. *Neurology*. 2000;55:490-7.

March 9, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Baylor University Medical Center (“BUMC”), we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital’s financial ability to provide this life-saving treatment to critically ill patients.

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

¹ American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

² Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563.

³ Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

⁴ The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke. Results of an international randomized trial. *New England Journal of Medicine*. 1985; 313:1191-1200.

Since Wingspan/Gateway approval last fall, three candidates have presented for this procedure at BUMC. One gentleman, aged 54, sustained recurrent stenosis of his basilar artery within 3 months of conventional angioplasty, and suffered recurrent strokes despite maximum medical therapy. Another male, age 47, came to us following multiple strokes while on double antiplatelet therapy. Likewise, our 75-year-old female patient had a history of rapidly recurrent cerebral ischaemia while under proper conservative management.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

We have been able to treat 2 of the 3 patients above with the Wingspan/Gateway system. In both cases, good angiographic and clinical outcomes were seen, with no recurrent strokes or TIAs.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement. We anticipate that—due to age or disability—the majority of our patients will be Medicare-dependent.

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

⁶ Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

⁷ Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

BUMC has spent great effort in becoming one of only two JCAHO-certified primary stroke centers in the Dallas-Fort Worth area, and as such we strive to afford the most advanced and effective range of therapies possible to community. Our 700 annual patient admissions for stroke management are the largest of any hospital in our 5 million population metropolitan area, and that number is rapidly growing. Nevertheless, the institution has limited resources with which to fund innovative treatments, and our ability to provide intracranial revascularization services will be severely limited without CMS support.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Ike Clayton Thacker, MD
Joseph H. Hise, MD

Diagnostic & Interventional Neuroradiology

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

March 7, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of University Hospitals of Cleveland, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

¹ American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

² Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563

³ Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

Since 2000 we have treated approximately 30 patients at our institution who have medical refractory symptomatic ICAD. A typical patient profile is as follows: A patient with a severe mid basilar artery stenosis who develops recurrent posterior circulation stroke symptoms despite optimal anticoagulation and blood pressure management. In this patient the only option of preventing inevitable neurological devastation is angioplasty and stenting.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷ In our experience, the Wingspan/Gateway system is ideal for the treatment of ICAD due to its well engineered ability to access intracranial lesions as well as its atraumatic delivery profile.

Under the current non-coverage policy, our institution is financially constrained in its ability to provide ICAD treatment with the Wingspan stent/Gateway balloon catheter system or any other stent system.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

University Hospitals of Cleveland is a tertiary referral center which services a potential patient base of more than 1.5 million. We admit approximately 1500 acute stroke cases per year, of these approximately 100-150 are due to ICAD. Many of these patients can be managed with medical therapy. However, for those in whom medical therapy is

⁴ The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke. Results of an international randomized trial. *New England Journal of Medicine*. 1985; 313:1191-1200.

⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

⁶ Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

⁷ Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

ineffective, the current non-coverage policy severely limits our option to provide beneficial therapy.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Himanshu Pandya, M.S., M.S.M.
Administrative Director
Department of Radiology
University Hospitals of Cleveland

HP/hre

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

March 7, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of University Hospitals of Cleveland, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

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³ Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

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In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷ In our experience, the Wingspan/Gateway system is ideal for the treatment of ICAD due to its well engineered ability to access intracranial lesions as well as its atraumatic delivery profile.

Under the current non-coverage policy, our institution is financially constrained in its ability to provide ICAD treatment with the Wingspan stent/Gateway balloon catheter system or any other stent system.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

University Hospitals of Cleveland is a tertiary referral center which services a potential patient base of more than 1.5 million. We admit approximately 1500 acute stroke cases per year, of these approximately 100-150 are due to ICAD. Many of these patients can be managed with medical therapy. However, for those in whom medical therapy is

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⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

⁶ Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

⁷ Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

ineffective, the current non-coverage policy severely limits our option to provide beneficial therapy.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative. If you have any questions, please feel free to contact me at 216-844-5722.

Sincerely,

Claudia Kraly, B.S., CNMT
Manager, Operations
Department of Radiology
University Hospitals of Cleveland

CK/hre

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

As a Clinical Fellow of the Interventional Neuroradiology/Endovascular Neurosurgery group at the Massachusetts General Hospital in Boston, we request that CMS issue an expeditious, positive national coverage decision for intracranial angioplasty and stenting in patients who receive treatment with the Humanitarian Use Device: the Wingspan Stent System with Gateway PTA Balloon Catheter. It should be noted that the request is specific to this device because it has received HDE clearance. If other devices were available we would request them as well.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experience in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days; 25% at 1 year), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

Over the last two years we felt compelled to use coronary stents in three cases of intracranial stenosis in the setting of recurrent strokes despite best medical management. Coronary stents, however, are not designed to be use in the cerebral vasculature which is typically more tortuous and more prone to vessel rupture or dissection than the coronary or peripheral vessels.

¹ American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

² Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563.

³ Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

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In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan Stent System with Gateway PTA Balloon Catheter under a Humanitarian Device Exemption (HDE). The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

In our practice, as well as nationally, intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement. It is also not economically feasible to expect patients to assume these direct costs.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients. It is obvious that the current Medicare non-coverage policy does not allow hospitals to provide this meaningful therapy.

⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

⁶ Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

⁷ Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Albert Yoo, MD
Clinical Fellow: Interventional Neuroradiology/Endovascular Neurosurgery
Massachusetts General Hospital
55 Fruit Street
Boston, MA 02114

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Memorial Regional Hospital, Hollywood, FL, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Intracranial atherosclerotic disease is an important contributor to the huge patient population with stroke. While it may not be the leading cause, it is the one that - until now – did not have a treatment method that addressed the mechanical cause of the disease. Similar treatment methods for coronary artery disease, for peripheral artery disease and even for the carotid arteries exist and are reimbursed.

Today ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Approximately 20 to 25% of patients with symptomatic ICAD suffer a debilitating second stroke within a year, resulting in an annual \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

It's heartbreaking to see that some of our patients, while on a waiting list for the Wingspan device, develop new strokes because medical therapy fails. These patients gradually lose their physical and mental abilities. Their mortality is predictable based on the severity of narrowing seen on angiograms. Based on clinical research data, approximately 90% of these patients can be saved if treated with intracranial stents.

Here at Memorial Regional Hospital in Hollywood, Florida we decided long time ago to join the ever-growing number of physicians who perform intracranial stent procedures with the Wingspan stent system.

South Florida's high elderly population and the high percentage of black and Hispanic population result in higher than average number of ICAD cases in our community; the number of cases is approximately 50% to 100% higher than in the average US population. Our hospital

administration is very supportive regarding intracranial stenting. We have a professional team that could provide a service for ICAD patients that's second to none. Unfortunately, despite our every effort, the procedure may not help all those patients who need it if it is not reimbursed. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Dr. Hoang Duong
Director, Interventional Neuroradiology
Memorial Regional Hospital

Dr. Laszlo Miskolczi
Interventional Neuroradiologist
Memorial Regional Hospital

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Abbott-Northwestern Hospital, a part of Allina Hospital and Clinics system, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, is a synopsis of some of the clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

¹ American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

² Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563.

³ Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

⁴ The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke. Results of an international randomized trial. *New England Journal of Medicine*. 1985; 313:1191-1200.

A typical patient seen at Abbott-Northwestern Hospital is a patient that has had recurrent small or a larger acute stroke that has been refractory to traditional medical management. After successful angioplasty and stenting they commonly return to their home in need of little additional care. The frequency of hospital readmissions for exacerbation of their symptoms is far less and lastly the frequency of office visit is less due to the ability for most of these patients to discontinue Coumadin.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment raising inappropriate conflicts in interests.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

The impact on our facility is especially important as Abbott-Northwestern is the largest hospital in Minneapolis and Allina Hospitals and Clinics is the largest provider services in the Minneapolis/St Paul area (3 million people, service area 5 million people). We are the largest endovascular service provider for neurovascular care. Abbott-Northwestern Hospital has consistently been ranked as one of the top hospitals for neurologic services (2005 16th in USA) as well as a top stroke hospital, given a 5-star rating by Health Grades. Both having an FDA approved device and reimbursement policy allows patients to receive the care that they deserve. Clearly non-coverage policy restricts access care to patients that have medical refractory symptomatic intracranial atherosclerosis and inhibits our ability to provide care that is known to be appropriate and available.

⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

⁶ Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

⁷ Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

There is enough evidence to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Gwen Nazarian, M.D.
Chief, Section of Interventional Radiology
Abbott Northwestern Hospital

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of St Joseph's Hospital and the Barrow Neurological Institute (Phoenix, AZ), we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If

¹ American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

² Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563.

³ Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

⁴ The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke. Results of an international randomized trial. *New England Journal of Medicine*. 1985; 313:1191-1200.

medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

In the Phoenix metropolitan area there is a large elderly population and consequently a large number of patients who would benefit from the use of this device. Such patients remain at exceedingly high-risk of stroke, which in and of itself, poses a huge financial burden on patients' families and hospitals alike.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁴ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁴ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁴

Our institution, the Barrow Neurological Institute, has partnered with the Cleveland Clinic and State University of New York (Buffalo) in reviewing our initial clinical experience with the use of this device in 30 patients. In all cases the device was deployed successfully and no patients suffered permanent complications as a result of its use.

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

⁶Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

⁷ Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

Our institution is the only hospital that provides daily endovascular neurosurgical coverage in the Phoenix metropolitan area, which has currently surpassed Philadelphia as the fifth largest city in the United States.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁴ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

⁸Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,
Felipe C. Albuquerque, MD
Assistant Director
Endovascular Neurosurgery
Barrow Neurological Institute
St. Joseph's Hospital
Phoenix, AZ



Department Interim Chair
Charles F. Lanzieri, MD, FACR, MBA

March 11, 2006

Diagnostic Radiology
Nannette M. Alvarado, MD
Nami Azar, MD
James N. Brennan, MD
Anne H. Coffey, MD
Joseph Crawford, MD
Baz P. DeBaz, MD
N. Carol Dornbluth, MD
Natalya Eidlin, MD
Arezou Faraji, MD
Melissa B. Frankel, MD
Donald J. Gordon, MD
John R. Haaga, MD
Nina L. Klein, MD
Sutek Lie, MD
Timothy Moore, MD
Andrew Myers, MD
Dean A. Nakamoto, MD
Sherif Nour, MD
Marisol Nunez-Hoyo, MD
Raj Mohan Paspulati, MD
Sharyl L. Pickering, MD
Donna M. Plecha, MD
Molly M. Yohann, MD
Hazel G. Young, MD

Cardiothoracic
Robert C. Gilkeson, MD
Peter B. Sachs, MD

Musculoskeletal
Mark R. Robbin, MD
Peter Young, MD

Neuroradiology
Charles F. Lanzieri, MD, MBA
Barbara A. Bangert, MD
Michael Coffey, MD
Jeffrey L. Sunshine, MD
Robert W. Tarr, MD

Nuclear Medicine
James K. O'Donnell, MD
Peter F. Faulhaber, MD
Robert Jones, MD
D. Bruce Sodee, MD
Lina Mehta, MD

Pediatric Radiology
Carlos J. Sivit, MD
Sheila C. Berlin, MD
Maria-Gisela Mercado-Deane, MD
Pauravi Vasavada, MD

Vascular Interventional
Adam H. Blum, MD
Freddy Drews, MD
Joseph P. LiPuma, MD
James Spain, MD

Basic Radiological Sciences
Jeffrey L. Duerk, PhD
Agata Exner, PhD
Baowei Fei, PhD
Zheng Hong Lee, PhD
Raymond F. Muzic, Jr., PhD
Pejavar S. Rao, PhD
Ron Novak, PhD

VA Medical Center
Craig George, MD
Preet S. Kang, MD

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

I kindly request that CMS issue an expeditious positive decision to cover intracranial stenting and angioplasty in patients who receive treatment. The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹ ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.²⁻⁴ If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

Since 2000 we have treated approximately 30 patients at our institution who have medical refractory symptomatic ICAD. A typical patient profile is as follows: A patient with a severe mid basilar artery stenosis who develops recurrent posterior circulation stroke symptoms despite optimal anticoagulation and blood pressure management. In this patient the only option of preventing inevitable neurological devastation is angioplasty and stenting. At present our institution must simply find away to offset the unsupported costs as we can not ethically deny the treatment.

¹ American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

² Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563

³ Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

⁴ The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high-grade stenosis who fail medical therapy for similar patients.¹⁽⁵⁾ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. In contrast to such off-label usage, on August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.^{(6)²} Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.^{(7)³} In our experience, the Wingspan/Gateway system is well suited for the treatment of ICAD due to its engineered ability to access intracranial lesions as well as its atraumatic delivery profile.

Again, under the current non-coverage policy, our institution is financially constrained in its ability to provide ICAD treatment with the Wingspan stent/Gateway balloon catheter system or any other stent system. This is especially true given that the equipment cost alone is about \$2000 for each Gateway balloon and \$6000 for each Wingspan stent!

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial cost in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

University Hospitals of Cleveland is a tertiary referral center, which services a potential patient base of more than 1.5 million. We admit approximately 1500 acute stroke cases per year, of these approximately 100-150 are due to ICAD. Many of these patients can be managed with medical therapy. However, for those in whom medical therapy is ineffective, the current non-coverage policy severely limits our option to provide beneficial therapy. In my opinion, there is now evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population, though some economic constraint on equipment cost may be warranted.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.^{(8)⁴} Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

⁶ Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

⁷ Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 70% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative. If you have any questions, please feel free to contact me at [REDACTED]

Sincerely,

Jeffrey L Sunshine, M.D. Ph.D.
Director of MRI and
Practicing Member of Interventional Neuroradiology
University Hospitals of Cleveland, University Hospitals Health System
Case Western Reserve University

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of **St Lukes Roosevelt hospital Center**, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until

¹ American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

² Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563.

³ Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

⁴ The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke. Results of an international randomized trial. *New England Journal of Medicine*. 1985; 313:1191-1200.

⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

Under FDA Humanitarian Device Exemption and our Institutional Review Board oversight we have helped significant high risk stroke patients with severe arterial vessel stenosis and no supporting collateral circulation using this device whereas in the past other methods of treatment carried higher risk of vessel rupture

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

⁶ Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

⁷ Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.


Sincerely;



Alex Berenstein, MD
MD



Yasunari Niimi, MD



Joon Song,

March 10, 2006

The Honorable Mark McClellan, M.D. PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 455-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA-Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of The Methodist Hospital, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: The Wingspan Stent System with Gateway PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke. If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

At our institution, we have been on the forefront in treating patients with intracranial atherosclerotic disease. Within the last two years The Methodist Hospital has formed The Methodist Neurological Institute, the fourth such institute of its kind in the entire country. A cornerstone of this institute is stroke. This includes intracranial as well as carotid bifurcation atherosclerotic disease processes. We were part of the initial SSylvia trial evaluating stenting and intracranial atherosclerotic disease, a study sponsored by Guidant Corporation. These patients are more difficult to treat than the common carotid atherosclerotic disease. They often continue to have TIA's in the face of maximum medical therapy. The only treatment option in the past has been to perform a superficial temporal to middle cerebral artery bypass graft. Indeed, in the acute stroke situation, the possibility of placing an intracranial stent has been a remarkable achievement. I have three such patients who were outside the window for intravenous TPA administration with large vessel occlusions but I was able to open a small channel to find the underlying stenosis. In each of these patients placement of a stent resulted in the immediate restoration of flow and all of these patients went on to make remarkable recoveries. Indeed one

patient was recently on a golf course talking about the hospital. It turns out he was talking to one of my partners about his stroke and placement of an intracranial stent. You cannot imagine the impact on these patients who could only receive medication before but now have hope for a complete recovery.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy. Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan Stent System with Gateway PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions. Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.

The Wingspan System

Since its introduction in November, I have used The Wingspan System on eleven patients. Four of these patients were recalcitrant to medical therapy and could not be safely treated with coronary stents. In three of the patients I tried to navigate a Taxus or Cypher stent and they would not move beyond the carotid syphon. The Wingspan system has been a remarkable achievement. With this stent we can now treat intracranial atherosclerotic disease that we could not dream of treating in the past. Every one of these patients has done remarkably well and all of these patients have had remarkable recoveries. There have been no adverse events. I have had no complications. After using this system I would be reticent to enroll my patients even in a double blinded level one randomized trial because I know these patients do so much better with placement of the stent and I know that this system works and is easy to use.

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

As a large tertiary referral medical center, we provide the majority of endovascular services to the community. The hospital size is over a thousand beds and with the advent of The Neurologic Institute our patient population is increasing. Our hospital has a commitment to treating stroke. Recently it has received The JCAHO Stroke Certification Center. There is a dedicated stroke team and a dedicated stroke floor. There will be a tremendous impact on having an FDA approved device to hospitals policy providing the procedure since it not presently reimbursable. The hospital assumes the cost of the procedure right now because it feels very strongly of its benefit to the community.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population. Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Richard P. Klucznik, M.D.
Director, Interventional Neuroradiology
The Methodist Neurological Institute
Director, Texas Neurovascular Center
Clinical Associate Professor of Radiology
Weill Cornell Medical School

RPK/sg

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

As a member of Abbott-Northwestern Hospital (a part of Allina Hospital and Clinics) medical staff and a practicing interventional neuroradiologist, I kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, is a synopsis of some of the clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

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A typical patient seen at Abbott-Northwestern Hospital is a patient that has had recurrent small or a larger acute stroke that has been refractory to traditional medical management. After successful angioplasty and stenting they commonly return to their home in need of little additional care. The frequency of hospital readmissions for exacerbation of their symptoms is far less and lastly the frequency of office visit is less due to the ability for most of these patients to discontinue Coumadin.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment raising inappropriate conflicts in interests.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

The impact on our facility is especially important as Abbott-Northwestern is the largest hospital in Minneapolis and Allina Hospitals and Clinics is the largest provider services in the Minneapolis/St Paul area (3 million people, service area 5 million people). We are the largest endovascular service provider for neurovascular care. Abbott-Northwestern Hospital has consistently been ranked as one of the top hospitals for neurologic services (2005 16th in USA) as well as a top stroke hospital, given a 5-star rating by Health Grades. Both having an FDA approved device and reimbursement policy allows patients to receive the care that they deserve. Clearly non-coverage policy restricts access care to patients that have medical refractory symptomatic intracranial atherosclerosis and inhibits our ability to provide care that is known to be appropriate and available.

⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

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The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Arvind Nehra MD

Consulting Radiologists, LTD.

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

As a neurointerventional radiologist at Abbott-Northwestern Hospital, a part of Allina Hospital and Clinics system, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, is a synopsis of some of the clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

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A typical patient seen at Abbott-Northwestern Hospital is a patient that has had recurrent small or a larger acute stroke that has been refractory to traditional medical management. After successful angioplasty and stenting they commonly return to their home in need of little additional care. The frequency of hospital readmissions for exacerbation of their symptoms is far less and lastly the frequency of office visit is less due to the ability for most of these patients to discontinue Coumadin.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment raising inappropriate conflicts in interests.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

The impact on our facility is especially important as Abbott-Northwestern is the largest hospital in Minneapolis and Allina Hospitals and Clinics is the largest provider services in the Minneapolis/St Paul area (3 million people, service area 5 million people). We are the largest endovascular service provider for neurovascular care. Abbott-Northwestern Hospital has consistently been ranked as one of the top hospitals for neurologic services (2005 16th in USA) as well as a top stroke hospital, given a 5-star rating by Health Grades. Both having an FDA approved device and reimbursement policy allows patients to receive the care that they deserve. Clearly non-coverage policy restricts access care to patients that have medical refractory symptomatic intracranial atherosclerosis and inhibits our ability to provide care that is known to be appropriate and available.

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To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

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Sincerely,

David Tuman MD, FACR
Consulting Radiologists, LTD.

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

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Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Abbott-Northwestern Hospital, a part of Allina Hospital and Clinics system, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

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Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Kevin Edelman, M.D.
Consulting Radiologists, LTD.

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Department of Health and Human Services
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Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Abbott-Northwestern Hospital, a part of Allina Hospital and Clinics system, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

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In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment raising inappropriate conflicts in interests.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

The impact on our facility is especially important as Abbott-Northwestern is the largest hospital in Minneapolis and Allina Hospitals and Clinics is the largest provider services in the Minneapolis/St Paul area (3 million people, service area 5 million people). We are the largest endovascular service provider for neurovascular care. Abbott-Northwestern Hospital has consistently been ranked as one of the top hospitals for neurologic services (2005 16th in USA) as well as a top stroke hospital, given a 5-star rating by Health Grades. Both having an FDA approved device and reimbursement policy allows patients to receive the care that they deserve. Clearly non-coverage policy restricts access care to patients that have medical refractory symptomatic intracranial atherosclerosis and inhibits our ability to provide care that is known to be appropriate and available.

⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

⁶ Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

⁷ Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

There is enough evidence to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Geoffrey D. Raile, MD
Consulting Radiologists, LTD.

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Abbott-Northwestern Hospital, a part of Allina Hospital and Clinics system, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, is a synopsis of some of the clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

¹ American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

² Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563.

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In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment raising inappropriate conflicts in interests.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

The impact on our facility is especially important as Abbott-Northwestern is the largest hospital in Minneapolis and Allina Hospitals and Clinics is the largest provider services in the Minneapolis/St Paul area (3 million people, service area 5 million people). We are the largest endovascular service provider for neurovascular care. Abbott-Northwestern Hospital has consistently been ranked as one of the top hospitals for neurologic services (2005 16th in USA) as well as a top stroke hospital, given a 5-star rating by Health Grades. Both having an FDA approved device and reimbursement policy allows patients to receive the care that they deserve. Clearly non-coverage policy restricts access care to patients that have medical refractory symptomatic intracranial atherosclerosis and inhibits our ability to provide care that is known to be appropriate and available.

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There is enough evidence to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Subbarao Inampudi, MD, FACR
Consulting Radiologists, LTD.

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Abbott-Northwestern Hospital, a part of Allina Hospital and Clinics system, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, is a synopsis of some of the clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

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In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

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Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

The impact on our facility is especially important as Abbott-Northwestern is the largest hospital in Minneapolis and Allina Hospitals and Clinics is the largest provider services in the Minneapolis/St Paul area (3 million people, service area 5 million people). We are the largest endovascular service provider for neurovascular care. Abbott-Northwestern Hospital has consistently been ranked as one of the top hospitals for neurologic services (2005 16th in USA) as well as a top stroke hospital, given a 5-star rating by Health Grades. Both having an FDA approved device and reimbursement policy allows patients to receive the care that they deserve. Clearly non-coverage policy restricts access care to patients that have medical refractory symptomatic intracranial atherosclerosis and inhibits our ability to provide care that is known to be appropriate and available.

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To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Stephen M. Fry, M.D.
Neuroradiologist
Consulting Radiologists, LTD.
1221 Nicollet Ave., Suite 600
Minneapolis, MN 55403

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Abbott-Northwestern Hospital, a part of Allina Hospital and Clinics system, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

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There is enough evidence to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

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To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

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Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Norman Arslanlar, DO
Neuroradiologist
Consulting Radiologists, LTD.

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

SAMPLE COMMENT TEMPLATE

COMMENTS DUE TO CMS NO LATER THAN March 11, 2006



The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of **St Paul Radiology**, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

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SAMPLE COMMENT TEMPLATE

COMMENTS DUE TO CMS NO LATER THAN March 11, 2006

We have, over the years, seen many patients with intracranial stenosis who have failed management with medication. Prior to this stent we has very little options for treatment. We would occasionally if necessary use coronary stents for these patients however these are difficult to use in the intracranial vasculature. The Wingspan stent and PTA balloon have provided us a way to treat patients with very few options. We have used the stent now on four patients and have found it to be easy to deploy and very low risk. Thus far these patients have done very well.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

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SAMPLE COMMENT TEMPLATE

COMMENTS DUE TO CMS NO LATER THAN March 11, 2006

We are one of the few Interventional Neuroradiology groups in Minnesota and the surrounding area. We are often the final option for these patients who are symptomatic and have failed conservative management. It unfortunately is a financial hardship for the patients to cover costs for these types of procedures. The hospitals and doctor groups cannot take on the financial risk.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

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Thank you again for your time and attention to this important public health policy initiative.
Sincerely,

Michael Madison, MD
Interventional Neuroradiology

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

**Piedmont Hospital
1968 Peachtree Road, NW
Atlanta, Georgia 30309**

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Piedmont Hospital, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

We, at our institution, have had variable success in treating patients with ICAD with interventional techniques as a last ditch effort when medical therapy has failed. Our most pressing concern is the inability to get to the targeted area with a stent that will maintain vessel patency. This has been particularly true in the vertebro-basilar system where it is difficult to reach the targeted area with conventional stents (e.g. coronary stents) and angioplasty alone has been inadequate.

¹ American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

² Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563.

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⁴ The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke. Results of an international randomized trial. *New England Journal of Medicine*. 1985; 313:1191-1200.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement. It is, also, not reasonable for society to incur the costs of not treating patients in whom a stroke could be obviated.

It is our firm belief that in order to provide intracranial endovascular services to our community, we must be able to use devices such as the Wingspan. We are a 500 bed hospital with an active neurology and neurosurgery service. We have been involved in treating strokes using endovascular means for approximately 13 years and have been able to provide significant benefit to our patients.

While the number of patients will not nearly approach the size of the population treated for coronary artery disease or carotid extracranial disease, the effects of a stroke secondary to ICAD can and will be devastating in these individuals. Intracranial stenting should not be a first line defense, but the option should be available.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an

⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

⁶ Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

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unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.
Sincerely,

Louis H. Jacobs, M.D.
Vice Chairman,
Department of Radiology
Piedmont Hospital

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Central Dupage Hospital, Winfield IL, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial

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vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

We have received approval from our IRB to begin to treat indicated patients with the new Wingspan Stent System and Gateway Balloon catheter.

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

Our Hospital has made a major commitment to treating stroke patients in the Greater Chicago West Suburbs. We have built a brand new state of the art Neurointerventional Lab within that last year. We have been conducting a series of public information lectures on the indications and latest technologies for stroke treatment and prevention.

- **At the present time without reimbursement, our hospital is limited to how we can treat these patients. We have a mix of approximately 40% Medicare patients.**

As you know, there are patients that continue to suffer Strokes and Stroke symptoms despite being on Medications. These are the patients that Intracranial and Angioplasty and Stenting show promise.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

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To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Harish Shownkeen, MD
Director, Endovascular Surgical Neuroradiology
Central DuPage Hospital
25 North Winfield Rd
Winfield, IL 60190



SAMPLE COMMENT TEMPLATE

COMMENTS DUE TO CMS NO LATER THAN March 11, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of **St Paul Radiology**, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

We have, over the years, seen many patients with intracranial stenosis who have failed management with medication. Prior to this stent we has very little options for treatment. We would occasionally if necessary use coronary stents for these patients however these are difficult to use in the intracranial vasculature. The Wingspan stent and PTA balloon have provided us a way to treat patients with very few options. We have used the stent now on four patients and have found it to be easy to deploy and very low risk. Thus far these patients have done very well.

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Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

We are one of the few Interventional Neuroradiology groups in Minnesota and the surrounding area. We are often the final option for these patients who are symptomatic and have failed conservative management. It unfortunately is a financial hardship for the patients to cover costs for these types of procedures. The hospitals and doctor groups cannot take on the financial risk.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an

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unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.
Sincerely,

James K. Goddard, MD
Interventional Neuroradiology

March 10, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

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The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, is provided the clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke. If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life. Surgical bypass has been shown to not be effective in the population and balloon angioplasty along carried potential high risk of neurologic injury at the time of the procedure.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy. Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions. Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.

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There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

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- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.
Sincerely,

Keith R. Peters, MD
Associate Professor of Radiology
Box 100374
Gainesville, FL 32610-0374



UNITED
HOSPITAL

Allina Hospitals & Clinics

March 10, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of United Hospital, St. Paul MN, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

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We have many patients with intracranial atherosclerotic disease who are currently failing maximal medical therapy and who would potentially benefit from these devices.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

United Hospital has used the Wingspan Stent System in two cases. Both of those cases went well and we believe that this product has potential to be beneficial.

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. The average cost per case can range from \$20,000 to \$40,000 depending on the number of stents inserted and the length of the inpatient stay. Therefore, it is not economically feasible for hospitals to allow these procedures to be performed without reimbursement.

United Hospital is the largest hospital in the Twin Cities east metro area, providing a full range of health care services to more than 200,000 people each year. Neurological disorders, such stroke, brain tumor and epilepsy, account for more hospitalizations than any other disease group, including heart disease and all types of cancer combined. The John Nasseff Neuroscience Institute is the center that brings together all of United's neuroscience programs including care for the stroke patient. United Hospital provides services for over 500 stroke patients per year. United Hospital offers a multidisciplinary approach to stroke and neurovascular services. Rapid evaluation and treatment by our stroke team in the Emergency Department followed by comprehensive inpatient care and stroke rehabilitation is protocol driven to streamline and accelerate the diagnosis and treatment.

Team includes:

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- Neurologists with expertise in stroke and neurovascular management
- Experienced Emergency department team (physicians and nurses)
- Neuro-radiologists
- Interventional neuro-radiologists
- Neurosurgeons
- Neuro-pathologist
- Inpatient nursing staff including care coordinators
- Stroke rehabilitation specialists provided by Sister Kenny Rehabilitation Institute (physiatrists, nurses and therapists)
- Nutritionists and social workers

Technology/Facilities include:

- Emergency department
- Neurointerventional biplane suite
- Advanced medical imaging capabilities including, 3T MRI, MRI Spectroscopy and PET scanning services
- Cardiac monitoring and testing
- Inpatient nursing unit care including ICU, telemetry units and dedicated 12 bed neurology unit.
- 16 bed Inpatient rehabilitation unit
- Neurodiagnostic lab – including intraoperative EEG monitoring

Treatments include:

- Thrombolytic drug TPA
- Endarterectomy
- Carotid and vertebral artery angioplasty and stenting
- Interventional cerebral angiography
- Neurosurgical interventions

This procedure uses a great deal of resources to provide excellent care. Lack of reimbursement negatively affects our ability to provide this service for our patients. Furthermore, lack of reimbursement will require patients to pay for this procedure out of pocket and in many situations would make the procedure cost prohibitive.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative. If you have any questions, please feel free to contact Susan Olson, Director, United Hospital John Nasseff Neuroscience Institute, at [REDACTED] or Don Johanns, Director of Medical Imaging at [REDACTED].

Sincerely,



Don Johanns
Medical Imaging Director



Susan Olson, M.S.
John Nasseff Neuroscience Institute Director

Avi Mazumdar, M.D.
Assistant Professor
University of Chicago
1335 South Prairie Avenue
Chicago, IL 60605

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of the University of Chicago and Hinsdale Hospital, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States. In the University of Chicago population, comprised of ethnic minorities, the available data suggests the incidence is higher still. Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke." If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life. In patients in whom medical therapy has failed the risk for recurrent stroke is reported to be as high as 40%.

After Extracranial-Intracranial bypass was shown to be ineffective for the treatment of intracranial atherosclerotic disease, there has been no effective treatment for this subset of patients. Even the recent WASID trial comparing aspirin to coumadin in the management of these patients showed an unacceptably high stroke rate.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy. Until

recently the only available devices were coronary devices (balloon mounted stents), used in an off label fashion, that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions. Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.

Prior to the development of the Wingspan stent system, we were often forced to use systems designed for the coronary circulation to treat patients with intracranial atherosclerotic lesions refractory to medical management.

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population. Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

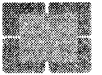
To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative.

Sincerely,

Avi Mazumdar
Assistant Professor Neuroradiology
University of Chicago Hospital



Peter A. Rasmussen, MD
Head, Sections of Cerebrovascular
and Endovascular Neurosurgery
Associate Professor, Cleveland Clinic Lerner College
of Medicine of Case Western Reserve University
Department of Neurosurgery/S80

March 7, 2006

The Honorable Mark McClellan, MD PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of the Cleveland Clinic, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If

¹American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

²Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. Circulation. 2006; 113:555-563.

medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

- Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

The non-coverage policy has had significant impact already on our institution in that the expected costs of these procedures are quite high. Given the size of the patient population at risk, it can be an institutional hardship, but not one for the federal government. In order to provide state-of-the-art care, coverage of the procedures is becoming mandatory.

³Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

⁴The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke. Results of an international randomized trial. *New England Journal of Medicine*. 1985; 313:1191-1200.

⁵Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

⁶Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

⁷Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

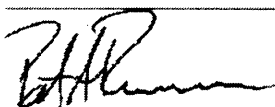
The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

1. National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
2. National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative. If you have any questions, please feel free to contact me via phone or email at

Sincerely,



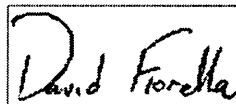
Peter A. Rasmussen, MD, Section Head



Henry H. Woo, MD



Thomas J. Masaryk, MD



David J. Fiorella, MD

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.



March 1, 2006

The Honorable Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA – Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Borgess Health, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.¹ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption.

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

¹ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

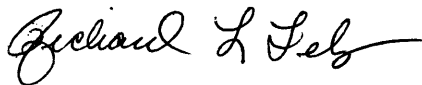
There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:

- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative. If you have any questions, please feel free to contact at [REDACTED]

Sincerely,



Richard L. Felbinger
Vice President & Chief Financial Officer

Control



2006 MAR 10 AM 12:00

3500 Gaston Avenue
Barnett Tower, Suite #220
Dallas, TX 75246
214-820-8158

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: NCA - Intracranial Stenting and Angioplasty (CAG-00085R2)

Dear Dr. McClellan:

On behalf of Baylor University Medical Center, we kindly request that CMS issue an expeditious, positive national coverage decision for intracranial stenting and angioplasty in patients who receive treatment with the Humanitarian Use Device: the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter.

The current national non-coverage policy directly affects our hospital's financial ability to provide this life-saving treatment to critically ill patients.

Below, we provide clinical background and our institution's current experiences in caring for patients with intracranial atherosclerotic disease (ICAD).

ICAD is the narrowing of blood vessels within the brain due to the build up of plaque. ICAD accounts for 8-10% of all ischemic strokes in the United States.¹ Stroke is the third leading cause of death in the U.S. (mortality rate, 7.6% at 30 days), and it is the leading cause of long-term disability. The annual cost is about \$51 billion in direct medical costs and indirect costs including losses in productivity.¹

Most ICAD stroke patients are typically treated with medical therapy but in some cases this therapy is ineffective and patients are left at a high risk for another stroke. Studies have shown a rate for some populations of 22.5% to as high as 24% in the year after their stroke.^{2,3,4} If medical therapy fails, there are limited treatment options, and these individuals suffer compromised quality of life.

¹ American Heart Association. Heart and Disease Stroke Statistics: 2005 Update. Dallas TX: American Heart Association; 2005; page 2.

² Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. Circulation. 2006; 113:555-563.

³ Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. Neurology 1995; 45:1488-1493.

⁴ The EC/IC Bypass Study Group. Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke. Results of an international randomized trial. New England Journal of Medicine. 1985; 313:1191-1200.

In fact, this week we treated a middle-aged man who suffered recurrent stroke attributable to severe intracranial atherosclerosis despite adequate medical therapy. Given his young age and failure of optimal medical management this patient would certainly be at extremely high risk for recurrent and likely severely disabling stroke. This is the prime example of a patient requiring intracranial angioplasty and stenting in order to reduce morbidity/mortality related to recurrent strokes. Reimbursement of these procedures will ultimately lead to reduced net costs by limiting further acute hospitalizations, long-term care costs and loss of productivity by reducing recurrent stroke rates. We performed angioplasty and stenting simply because it the medically appropriate treatment, however the financial losses incurred under the current non-coverage policy will preclude universal usage of this function-sparing and potentially life-saving procedures.

In the past decade, intracranial stenting and angioplasty has emerged as a promising therapy in symptomatic patients with high grade stenosis who fail medical therapy.⁵ Until recently the only available devices were coronary devices that were not designed or indicated for intracranial use. On August 3, 2005, the Food and Drug Administration approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter under a Humanitarian Device Exemption. The Wingspan Stent System is the first marketed self-expanding stent specifically designed for the intracranial vasculature. In the Wingspan HDE clinical study, there was a 97.7% procedural success rate and at one year post procedure, 90% of the patients were free of strokes related to their treated lesions.⁶ Early U.S. experience reported at the recent American Stroke Association meeting shows a similar acute procedural profile.⁷

Under the current non-coverage policy, our institution is financially constrained in its ability to provide this ICAD treatment.

Intracranial angioplasty and stenting is performed in the hospital inpatient setting, usually under general anesthesia. Absent Medicare reimbursement, our institution assumes significant financial risks in treating ICAD patients. Similar to craniotomy procedures, intracranial angioplasty interventions involve a full operating room contingency, including nursing personnel, anesthesiologists, special procedure technologists, and circulating personnel. It is not economically feasible for the hospital to allow these procedures to be performed without reimbursement.

Baylor University Medical Center is a JCAHO certified primary stroke center and functions as the major comprehensive stroke center in the Dallas region. We are the main providers of neuroendovascular services in the region including intra-arterial revascularization, aneurysm clipping and arteriovenous malformation embolizations. The Baylor Stroke Program is committed to treatment of all patients with cerebrovascular disease and participates in the Dallas Stroke Network. In fact, Baylor University Medical Center receives the largest number of

⁵ Schumacher HC et al. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. *Journal of Vascular and Interventional Radiology*. 2004; 15:S123-S132.

⁶ Hartmann M et al. One Year Stroke Risks in High Grade, Symptomatic, Medically Refractory Intracranial Atherosclerosis after Angioplasty and Stenting: The Wingspan™ Trial. Poster Presentation. International Stroke Conference 2006. American Stroke Association. February 2006.

⁷ Rasmussen P. Evidence-based Management of Cerebrovascular Disease. Case discussion on early U.S. experience at three institutions: Cleveland Clinic, Barrow Neurological Institute, and SUNY Buffalo. International Stroke Conference 2006. American Stroke Association. February 17, 2006.

ambulance transported stroke patients within the network, treating more than 700 stroke patients annually. Our ability to perform intracranial angioplasty and stenting will have a definite impact of the Dallas community.

There is now enough evidence available to warrant national Medicare coverage for a treatment that benefits an orphan disease population.

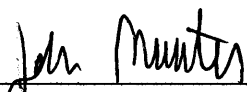
The interventional professional societies, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology, and the American Society of Neuroradiology, support health insurer coverage for the symptomatic medically refractory ICAD patient population.⁸ Given that these patients lack other treatment options and face an unacceptable risk of another stroke, the availability of endovascular treatment using the Wingspan stent is critical to patient care, and CMS should provide coverage for these patients.

To continue to provide this life-saving treatment option, we request that CMS act quickly to reverse its non-coverage policy and ask for the following:


- 1) National Medicare coverage of PTA and stenting of cerebral arteries when performed in vessels with greater than or equal to 50% stenosis for patients who are refractory to medical therapy, concurrent with use of a device approved for marketing by the FDA (subject to any requirements established by the applicable FDA approval or clearance process) for this specific indication, and
- 2) National Medicare coverage for intracranial stenting and angioplasty within the context of a category B investigational device exemption (IDE) clinical trial.

Thank you again for your time and attention to this important public health policy initiative. If you have any questions, please feel free to contact me at [REDACTED] or [REDACTED]

Sincerely,



John McWhorter
President
Baylor University Medical Center



Lise Labiche, MD
Director, Stroke Program
Baylor University Medical Center

⁸ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.