



**Tracking Form for Applicants for New Technology Add-on Payments under
the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal
Year (FY) 2008**

1. Technology Name:

Intracranial Atherosclerotic Stent System with Intracranial Percutaneous Transluminal
Angioplasty Balloon Catheter

2. Manufacturer Name:

Boston Scientific Corporation
47900 Bayside Parkway
Fremont CA 94538

3. Trade Brand of Technology:

Wingspan[®] Stent System with Gateway[™] PTA Balloon Catheter

4. Brief Description of Service or Device:

Intracranial stenting and angioplasty provides a treatment option for patients who are medically refractory, suffer from intracranial atherosclerotic disease, and face no other therapeutic alternatives. The procedure involves neuroendovascular treatment of intracranial atherosclerotic lesions using a microcatheter-based interventional technique.

(For the complete application requirements, please see the instructions at
http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp)

Note: The information provided on this tracking form will be made publicly available.

New Criteria

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the diagnosis related groups (DRGs).

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

The FDA approved the Wingspan® Stent System with Gateway™ PTA Balloon Catheter on August 3, 2005 under a Humanitarian Device Exemption (HDE), which is an approval pathway for treatments that affect fewer than 4,000 individuals annually in the United States (considered an “orphan” disease population).

6. Was the product available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation for any delay (i.e. manufacturing issues, shelf life concerns or other reasons).

No. Boston Scientific Corporation began marketing the Wingspan® Stent System in November 2005 according to a careful, limited launch to qualified academic centers and other hospital institutions within the United States with solid experience in neuroendovascular technique. Please see new technology add-on payment application for additional details.

7. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) or is an application pending?

a. If yes, please provide the ICD-9-CM procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

Yes. Effective October 1, 2004, CMS issued two new ICD-9-CM procedural codes to describe intracranial angioplasty and intracranial stenting procedures:

- 00.62 Percutaneous angioplasty or atherectomy of intracranial vessel(s)
- 00.65 Percutaneous insertion of intracranial vascular stent(s)

Prior to October 1, 2004, the predecessor codes for these procedures were:

- 39.50 Angioplasty or atherectomy of non-coronary vessel
- 39.90 Insertion of non-drug-eluting, non-coronary artery stent(s)

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b. If there is no existing ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01_overview.asp for more information.) We note that, if the product were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-9-CM code(s) in the MedPAR claims data in order to receive add-on payment.

Not applicable.

8. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. (Please refer to http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp for more information.)

No.

Cost Criteria

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned. Table 10 from the annual final rule lists the thresholds by DRG. The most recent version of Table 10 can be downloaded at: http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp.

Provide the following information to demonstrate the technology or service meets the criterion.

9. What is the anticipated average standardized charge per case involving this new technology? For details how to standardize charges please refer to the technical appendix of the application form.

We conducted two types of analyses in two sources of data (MedPAR 2005 data and aggregated Hospital Discharge 2005 Data from the states of California and Florida).

Tables 1 and 2 identify intracranial angioplasty and stenting cases in the MedPAR 2005 data. Specifically, Table 1 identified intracranial angioplasty cases based on new procedural code, 00.62, with these cases restricted to DRGs 533 and 534, where such cases are currently typically assigned.

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Table 1 (source: MedPAR 2005 data)

	Total	Mean	FY 08 Method	Mean
DRG	Discharges	LOS (Days)	Standardized Charges	Weighted Cost
Cases w/ 00.62 in DRG 533	35	8.1	\$54,576	\$33,000
Cases w/ 00.62 in DRG 534	< 11	2.2	\$29,638	\$17,086

Given the newness of 00.62 in the MedPAR data, we also examined intracranial angioplasty cases based on predecessor procedure code, 39.50, *Angioplasty or atherectomy of other non-coronary vessels*, with these cases restricted to DRGs 533 and 534. We further identified cases associated with intracranial atherosclerotic lesions according to relevant primary diagnosis codes. This analysis is shown in Table 2 and shows results consistent with the approach using the new procedure codes for intracranial angioplasty and stenting.

Table 2 (source: MedPAR 2005 data)

	Total	Mean	FY 08 Method	Mean
DRG	Discharges	LOS (Dys)	Standardized Charges	Weighted Cost
Cases w/ 39.50 + Primary Dx in DRG 533	577	8.3	\$54,984	\$26,775
Cases w/ 39.50 + Primary Dx in DRG 534	179	2.5	\$29,845	\$12,983

Please see new technology add-on payment application for further details on the Cost Criteria evaluation.

10. What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)? What is the cost of the technology per patient? Please provide a breakdown how the cost of the technology is calculated (i.e. Drugs- Average dosage or number of units per patient (ml/kg/hr); Devices- breakdown of the cost of all components used in the new technology, clearly showing which components are the “new” ones).

Please see new technology add-on payment application.

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11. List the diagnosis-related groups (DRGs) to which cases involving this new technology will most likely be assigned.

Both the new procedural codes, 00.62 and 00.65, and the predecessor procedural codes, 39.50 and 39.90, are currently assigned to DRGs 533 and 534 (Extracranial Procedures with and without Comorbidities and Complications).

However, we believe that the current DRG assignments are inappropriate, and intracranial angioplasty and stenting cases should be reassigned to alternate DRGs, which are more reflective of the clinical nature and resource demands of such neuroendovascular procedures. The more appropriate DRGs include DRGs 1 (Adult Craniotomy with Comorbidities and Complications), 2 (Adult Craniotomy without Comorbidities and Complications), and 543 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis).

12. What is the anticipated volume of Medicare cases involving this technology in FY 2008 (by DRG)?

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Clinical Improvement

Note: To qualify for a new technology add-on payment, the technology or service must represent a substantial clinical improvement over existing technologies or services

13. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.

a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

Intracranial angioplasty and stenting offers the only available treatment option to restore or maintain normal hemodynamics and decrease the risk of stroke for selected patients with intracranial atherosclerotic disease.

Intracranial atherosclerotic disease is associated with high rates of stroke and death. 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.^{1,2,3} There is no currently accepted surgical option that effectively lowers the risk of stroke to an acceptable level in these patients.³ In recent years, however, endovascular therapy with stents and balloons has demonstrated promising clinical results. To date, these procedures have primarily been performed using stainless steel, balloon expandable stents and balloons that were designed and approved by the FDA for coronary use. Long-term patient outcomes are now being reported in the literature to confirm that reductions in stroke rates persist over time with endovascular therapy.⁴

The Wingspan Stent System with Gateway PTA Balloon Catheter is the first commercially available stenting and balloon system in the U.S. that is specifically designed for intracranial use. The Wingspan Stent System is designed to reduce trauma to the parent vessel, reduce incidence of vessel restenosis, and reduce incidence of iatrogenic hemorrhage when compared to current angioplasty balloons and stents that were not designed for intracranial use. Please consult the new technology payment application for further explanation on substantial clinical improvement.

¹ Kasner et al. Predictors of Ischemic Stroke in the Territory of a Symptomatic Intracranial Arterial Stenosis. *Circulation*. 2006; 113:555-563.

² Chimowitz et al. The Warfarin-Aspirin Symptomatic Intracranial Disease Study. *Neurology* 1995; 45:1488-1493.

³ 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.

⁴ Marks MP et al. Intracranial Angioplasty without Stenting for Symptomatic Atherosclerotic Stenosis: Long-Term Follow-up. *AJNR Am J Neuroradiol* 26: 525-530, March 2005.

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b. List all published peer-review articles relevant to the new service or technology.

Key clinical literature include the following:

Alazzaz A et al. Intracranial percutaneous transluminal angioplasty for arteriosclerotic stenosis. *Arch Neurol.* 2000 Nov;57(11):1625-30.

Connors III JJ and Wojak JC. Percutaneous transluminal angioplasty for intracranial atherosclerotic lesions: Evolution of technique and short-term results. *J Neurosurg* 1999;91:415-423.

Engl J, *et al.* Intracranial Angioplasty and Stenting: Modern Approaches to Revascularization for Atherosclerotic Disease. *Neurosurgery Clinics of North America.* 2005; 16:297-308.

Higashida RT, et al. Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis : A Position Statement of the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, and the American Society of Neuroradiology. *J Vasc Interv Radiol.* 2005; 16:1281-1285. [Note: This position statement was also published in the October 2005 issue of the American Journal of Neuroradiology.]

Lylyk P, Cohen JE, Ceratto R, Ferrario A, Miranda C. Angioplasty and stent placement in intracranial atherosclerotic stenoses and dissections. *AJNR.* 2002;23:430-436.

Marks MP et al. Intracranial Angioplasty without Stenting for Symptomatic Atherosclerotic Stenosis: Long-Term Follow-up. *AJNR Am J Neuroradiol* 26: 525-530, March 2005.

Marks MP, Marcellus M, Norbash AM, Steinberg GK, Tong D, Albers GW. Outcome of angioplasty for atherosclerotic intracranial stenosis. *Stroke.* 1999;30:1065-1069.

Mori T, Fukuoka M, Kazita K, Mori K. Follow-up study after intracranial percutaneous transluminal cerebral balloon angioplasty. *Am J Neuroradiology.* 1998;19:1525-1533.

Mori T, Kazita K, Chokyu K, Mima T, Mori K. Short-Term arteriographic and clinical outcome after cerebral angioplasty and stenting for intracranial vertebrobasilar and carotid atherosclerotic occlusive disease. *AJNR.* 2000;21:249-254.

Nahser HC, Henkes H, Weber W, Berg-Dammer A, Kuhne D. Intracranial vertebrobasilar stenosis: Angioplasty and follow-up. *AJNR.* 2000;21:1293-1301.

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Schumacher HC, Khaw AV, Meyers PM, Gupta R, Higashida RT. Intracranial Angioplasty and Stent Placement for Cerebral Atherosclerosis. J Vasc Interv Radiol. 2004 Jan;15(1 Pt 2):S123-32.

SSYLVIA Study Investigators. Stenting of Symptomatic Atherosclerotic Lesions in the Vertebral or Intracranial Arteries (SSYLVIA): study results. Stroke. 2004 Jun;35(6):1388-92.

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