



**Tracking Form for Applicants for New Technology Add-on Payments under
the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal
Year (FY) 2013**

1. Technology Name: Fenestrated Endovascular Graft
2. Manufacturer Name: WILLIAM A. COOK AUSTRALIA PTY. LTD.
Distributed in the U.S. by Cook Medical
3. Trade Brand of Technology: Zenith® Fenestrated AAA Endovascular Graft
4. Brief Description of Service or Device:

The Zenith® Fenestrated AAA Endovascular Graft is an implantable device designed to treat abdominal aortic aneurysms in patients who are anatomically unsuitable for treatment with currently approved AAA endovascular grafts due to a short infrarenal aortic neck. It is a modular system consisting of three components: a two-part main body graft and one iliac leg. The two-part main body of the graft consists of a proximal tubular graft and a distal bifurcated graft body. The proximal body graft contains precisely located holes (fenestrations) and/or cut-outs from the proximal margin (scallop(s)) of the polyester graft material along with a bare proximal stent with barbs to provide fixation. The iliac leg component, which couples with the main bifurcated body, completes the basic fenestrated endograft.

Newness Criterion

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 Medicare severity diagnosis related groups (MS-DRGs).

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

Approval has not yet been granted for this device, though we anticipate approval before July 1, 2012.

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

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

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).

Approval has not yet been granted for this device. However, upon FDA approval, Cook Medical anticipates no delays in marketing the product.

7. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and/or ICD-10-PCS procedure code(s) or is an application pending?

- a. If yes, please provide the ICD-9-CM and/or ICD-10-PCS procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

The recently created (FY 2012) ICD-9-CM procedure code 39.78, *Endovascular implantation of branching or fenestrated graft(s) in aorta*, is reported to identify the clinical procedure in which this technology is used.

- b. If there is no existing ICD-9-CM and/or ICD-10-PCS 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#TopOfPage 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 and effective October 1, 2013 by ICD-10-PCS code(s) in the MedPAR claims data in order to receive add-on payment.

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#TopOfPage for more information.)

An outpatient application for pass-through payments under the Medicare outpatient prospective payment system has not been submitted nor does Cook Medical intend on applying for pass-through payment under the outpatient prospective payment system as this procedure is performed on an inpatient only basis.

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Cost Criterion

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 MS-DRGs to which the new technology is assigned. Table 10 from the annual final rule lists the thresholds by MS-DRG. The most recent version of Table 10 can be downloaded at: <https://www.cms.gov/AcuteInpatientPPS/FR2012/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1250507&intNumPerPage=10>.

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

8. 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.

This information is proprietary.

9. **A.** 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)?

This information is proprietary.

B. 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).

This information is proprietary.

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

On October 1, 2011 ICD-9-CM procedure code 39.78, *Endovascular implantation of branching or fenestrated graft(s) in aorta*, became effective and was classified into the following MS-DRGs:

- MS-DRG 252: Other Vascular Procedures with Major Complications and Comorbidities
- MS-DRG 253: Other Vascular Procedures with Complications and Comorbidities
- MS-DRG 254: Other Vascular Procedures without Complications and Comorbidities or Major Complications and Comorbidities
- MS-DRG 957: Other OR Procedures for Multiple Significant Trauma with MCC

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- MS-DRG 958: Other OR Procedures for Multiple Significant Trauma with CC
- MS-DRG 959: Other OR Procedures for Multiple Significant Trauma without CC/MCC

It is Cook Medical's belief, based on the principles of clinical coherence and "like" resource utilization, that Zenith Fenestrated AAA Endovascular procedures are more accurately aligned to MS-DRGs 237-238. It is also our understanding that the DRG assignment is under re-consideration for FY2013.

11. What is the anticipated volume of Medicare cases involving of this technology in FY 2013 (by MS-DRG)?

This information is proprietary

Clinical Improvement Criterion

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.

12. 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:

The Zenith Fenestrated graft has been developed to treat abdominal aortic aneurysms (AAA), a potentially deadly condition. This disease is prevalent in the Medicare beneficiary population. Abdominal aortic aneurysms are predominately a disease of the older population, affecting approximately 5% - 10% of men aged between 65 and 79 years, and approximately 75% of patients with AAA treated each year are Medicare beneficiaries. The condition is often asymptomatic and risk of aneurysm rupture, which is often fatal, increases with aneurysm size.

Most AAAs occur in the segment of aorta below the origin of the renal arteries. They are described as "infrarenal" AAAs, and most infrarenal AAAs requiring repair are treated with standard endovascular grafts rather than open surgery. However, standard endovascular grafts require a non-diseased segment of aorta below the renal arteries (the infrarenal "neck") of at least 10 to 15 mm in length. Patients with infrarenal necks < 10-15 mm may only be treated with open surgery, or watchful waiting/medical management if significant co-morbidities preclude open surgical repair.

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Treatment with the COOK Zenith® Fenestrated AAA Endovascular Device results in a substantial clinical benefit in the following ways:

- It offers a AAA repair option to those patients with short infra-renal necks who, because of severe co-morbidities, would not have been considered open surgical repair candidates and therefore would have had no other treatment option; and
- Compared to open surgical repair, it offers a less invasive treatment option for AAA patients with short infra-renal necks that results in:
 - Reduced mortality
 - Reduced morbidity
 - Shorter hospital stays, and
 - Shorter ICU stays

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

- i. Scurr J, Brennan J, Gilling-Smith G, Harris P, Vallabhaneni S, McWilliams R. Fenestrated Endovascular Repair for Juxtarenal Aortic Aneurysm. Br J Surg, 2008 Mar, 95(3): 326-32
- ii. Chuter T. Fenestrated and Branched Stent-Grafts for Thoracoabdominal, Pararenal and Juxtarenal Aortic Aneurysm Repair. Semin Vasc Surg 2007. 20:90-96
- iii. Bicknell C, Cheshire N, Riga C, Bourke P, Wolfe J, Gibbs R, Jenkins M, Hamady M. Treatment of Complex Aneurysmal Disease with Fenestrated and Branched Stent Grafts. Eur J Vasc Endovasc Surg 2009, 37: 175-181
- iv. Greenberg R, Sternbergh III W C, Makaroun M, Ohki T, Chuter T, Bharadwaj P, and Saunders A. Intermediate results of a United States multicenter trial of fenestrated endograft repair for juxtarenal abdominal aortic aneurysms. J Vasc Surg, 2009 Oct, 50(4): 730-737
- v. Sun Z, Muripatayi B, Semmens J, Lawrence-Brown M. Short to Mid-term Outcomes of Fenestrated Endovascular Grafts in the Treatment of Abdominal Aortic Aneurysms; a systematic review. J Endovasc Ther. 2006 Dec; 13(6): 747-53
- vi. Haulon, S., et al., An analysis of the French multicentre experience of fenestrated aortic endografts: medium-term outcomes. Ann Surg, 2010. 251(2): p. 357-62
- vii. Amiot, S., et al., Fenestrated endovascular grafting: the French multicentre experience. Eur J Vasc Endovasc Surg, 2010. 39(5): p. 537-44
- viii. Verhoeven, E.L., et al., Fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm: an 8-year single-centre experience. Eur J Vasc Endovasc Surg, 2010. 39(5): p. 529-36
- ix. Tambyraja, A.L., et al., Fenestrated aortic endografts for juxtarenal aortic aneurysm: medium term outcomes. Eur J Vasc Endovasc Surg, 2011. 42(1): p. 54-8.

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- x. Prinssen M, Verhoeven ELG, Buth J, Cuypers PWM, van Sambeek MRHM, Balm R, Buskens E, Grobbee DE, Blankensteijn JD. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. *The New England Journal of Medicine* 2004; 351: 1607-1618.
- xi. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial. *The Lancet* 2004; 364: 843-848.
- xii. Greenberg RK, Chuter TAM, Sternbergh C, Fearnot NE. Zenith AAA endovascular graft: intermediate-term results of the US multicentre trial. *Journal of Vascular Surgery* 2004; 39: 1209-1218
- xiii. Nordon, I.M., et al., Modern treatment of juxtarenal abdominal aortic aneurysms with fenestrated endografting and open repair--a systematic review. *Eur J Vasc Endovasc Surg*, 2009. 38(1): p. 35-41
- xiv. Wilderman M, Sanchez LA. Fenestrated grafts or debranching procedures for complex abdominal aortic aneurysms. *Perspect Vasc Surg Endovasc Ther*. 2009 Mar;21(1):13-8.
- xv. Chisci E, Kristmundsson T, et al. The AAA with a challenging neck: outcome of open versus endovascular repair with standard and fenestrated stent-grafts. *J Endovasc Ther*. 2009 16:137-146
- xvi. Kristmundsson T, Sonnesson B, et al. Fenestrated endovascular repair for juxtarenal aortic pathology. *J Vasc Surg* 2009;49:568-75
- xvii. Beck A, Bos, W, et al. Fenestrated and branched endograft repair of juxtarenal aneurysms after previous open aortic reconstruction. *J Vasc Surg* 2009;49:1387-94
- xviii. O'Neill S, Greenberg R, et al. A prospective analysis of fenestrated endovascular grafting: intermediate-term outcomes. *Eur J Vasc Endovasc Surg* 2006;32:115-123

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