

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850



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:

Drug-Eluting Peripheral Vascular Stent

2. Manufacturer Name:

Cook Ireland Ltd., Limerick, Ireland
Distributed in the U.S. by Cook Medical

3. Trade Brand of Technology:

Zilver[®] PTX[®] Drug-Eluting Peripheral Stent

4. Brief Description of Service or Device:

The Cook Zilver[®] PTX[®] Drug-Eluting Peripheral Stent is intended for use in the treatment of symptomatic vascular disease of the above-the-knee femoropopliteal arteries (superficial femoral arteries). The stent is coated with paclitaxel, a drug approved for use as an anti-cancer agent and used successfully with coronary stents to reduce the risk of re-narrowing of the coronary arteries after stenting procedures. In many stenting cases, patients experience a re-narrowing of the arteries over time, called "in-stent restenosis". This happens when cells grow around the stent - essentially creating scar tissue - and cause the blood vessel to narrow again. The Zilver[®] PTX[®] stent helps prevent this re-narrowing from occurring by inhibiting "intimal hyperplasia", this overgrowth of cells.

The Zilver[®] PTX[®] Drug Eluting Peripheral Stent is a self-expanding stent made of nitinol and coated with the drug paclitaxel. The stent is a flexible, slotted tube that is preloaded in a 6.0 or 7.0 French delivery catheter. The Zilver[®] PTX[®] stent is designed to provide support while maintaining flexibility in the vessel upon deployment. Post-deployment, the stent is designed to impart an outward radial force upon the inner lumen of the vessel, establishing patency in the stented region.

(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.

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.

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).

This product does not have FDA approval, however it will be available immediately after approval is granted.

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.

This technology is described by the recently created (FY 2010) ICD-9-CM Procedure code 00.60 – Insertion of drug-eluting stent(s) of the superficial femoral artery.

In addition, ICD-9- CM procedure codes 39.50 (Angioplasty or atherectomy of other non-coronary vessel(s), 00.40 (Procedure on a single vessel), 00.41 (Procedure on two vessels), 00.42 (Procedure on three vessels), 00.43 (Procedure on four or more vessels), 00.44 (Procedure on vessel bifurcation), 00.45 (Insertion of one vascular stent), 00.46 (Insertion of two vascular stents), 00.47 (Insertion of three vascular stents), and 00.48 (Insertion of four or more vascular stents) may also be coded along with 00.60 to describe this procedure.

- 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

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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.

See (a) above

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.)

No, we have not submitted an outpatient application for pass-through payments under the Medicare outpatient prospective payment system, as these applications can only be submitted after FDA approval is obtained.

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 is proprietary information

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 is proprietary information

- 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).

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

Peripheral vascular stent placement is performed in patients with peripheral vascular disease, as an adjunct to failed angioplasty, or as a primary treatment (typically following pre-dilation with an angioplasty balloon). Under the Medicare MS-DRG system, such patients may be classified to one of three possible MS-DRG groups. These MS-DRGs are listed below.

- 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 or Comorbidities or Major Complications or Comorbidities

The newly created (FY2011) ICD-9 code 00.60 has been assigned to these MS-DRGs

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

This is proprietary information

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 superficial femoral artery is a common site for peripheral arterial disease (PAD) to occur. The most common cause of lower limb PAD is atherosclerosis, with clinical progression being affected by a number of factors, including comorbidities such as diabetes. Patients with significant PAD unresponsive to conservative treatment and medical management require intervention. While treatment options exist, the rates of success are variable, resulting in high rates of reintervention for the most common catheter-based treatment modalities (angioplasty and/or bare metal stenting), and high rates of morbidity and

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mortality for bypass surgery. These mixed results have led to robust clinical debate over the most appropriate intervention.

COOK considers the Zilver PTX to offer a substantial clinical improvement over current minimally invasive, catheter-based treatments and open surgical bypass. Through the reduction in the incidence of re-stenoses following treatment of atherosclerotic SFA lesions, the Zilver PTX Drug-eluting Peripheral Stent offers a minimally-invasive treatment option that:

- decreases the recurrence of symptoms arising from re-stenotic SFA lesions;
- decreases the rate of subsequent diagnostic or therapeutic interventions required to address re-stenotic lesions; and
- decreases the number of future hospitalizations

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

Dake, M.D., Ansel, G.M., Jaff, M.R., Ohki, T., Saxon, R.R., Smouse, H.B., Zeller, T., Roubin, G.S., Burket, M.W., Khatib, Y., Snyder, S.A., Ragheb, A.O., White, J.K., Machan, L.S.(2011), Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month zilver PTX randomized study results. *Circulation Cardiovascular Interventions*, published online September 27, 2011, 495-504

Dake, M. D., Scheinert, D., Tepe, G., Tessarek, J., Fanelli, F., Bosiers, M., et al. (2011). Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: Twelve-month safety and effectiveness results from the zilver PTX single-arm clinical study. *Journal of Endovascular Therapy*, 18(5), 613-623

Dake, M. D., Van Alstine, W. G., Zhou, Q., & Ragheb, A. O. (2011). Polymer-free paclitaxel-coated Zilver PTX stents: evaluation of pharmacokinetics and comparative safety in porcine arteries. *Journal of Vascular and Interventional Radiology*, 22(5), 603-610

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