



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: UnBalloon Catheter
2. Manufacturer Name: LeMaitre Vascular
3. Trade Brand of Technology: The UnBalloon™ Non-Occlusive Modeling Catheter
4. Brief Description of Service or Device: The UnBalloon Non-Occlusive Modeling Catheter is intended to assist in the modeling of self expanding endoprotheses in large diameter vessels. The Unballoon catheter consists of a Nitinol mesh in a 14F retractable sheath. The Nitinol mesh design allows for expansion without occluding blood flow. The Nitinol mesh and radiopaque markers are highly visible under fluoroscopy and assist in the positioning of the device. The inner lumen allows for a 0.035 or 0.038 inch guidewire for over-the-wire access. Side ports and clear handle/luer allow the device and guidewire lumen to be flushed. The blue handle allows the device to be sheathed/unsheathed while the clear handle/luer controls the expansion of the Nitinol mesh.

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:

LeMaitre Vascular received 510K Clearance for the UnBalloon™ Non-Occlusive Modeling Catheter (K110891) on September 13, 2011. Please see the attached FDA clearance letter and summary of approval.

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).

The device was available immediately after FDA clearance.

(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.

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.

We believe the ICD-9-CM code applicable to our product is: 39.79 Other endovascular repair (of aneurysm) of other vessels, however this is very general. Please see our response below.

- 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.

To ensure we have a distinctly identifiable code, we will be applying for a new code.

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, an application has not been submitted for outpatient pass-through payments.

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.

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

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

We do not have a MS-DRG code at this time since we are unsure of our ICD-9-CM code.

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

We do not have a MS-DRG code at this time since we are unsure of our ICD-9-CM code.

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 UnBalloon differs from the predicate devices (Cook Coda Balloon Catheter, Medtronic Reliant Balloon Catheter, and Gore Tri-Lobe Balloon Catheter) as it is designed to eliminate the pressure that typically builds up on the proximal end of those devices when inflated. By eliminating occlusion (or partial occlusion), the risks associated with occlusion during ballooning of an endovascular prosthesis may be minimized, potentially allowing the surgeon to more accurately model grafts that have been deployed.

The UnBalloon is a coaxial design and therefore multiple catheters run through the length of the outer sheath. These catheters act as the mechanical actuators for expansion of the Nitinol cage at the distal end of the catheter.

A beta study was completed at 14 sites in Brazil and in the European Union. The attached interim report states the device performed successfully in 13 (4 thoracic and 9 abdominal) cases with no reported adverse events or device related malfunctions. In 11 of the 13 cases, the device met the user’s expectations.

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

This device does not have any published peer-reviewed articles relevant to the device or service.

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