



**Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2011**

1. Technology Name: *Intravascular Near Infrared Spectroscopy IVUS*
2. Manufacturer Name: *InfraReDx, Incorporated*
3. Trade Brand of Technology: *LipiScan™ IVUS*
4. Brief Description of Service or Device: *LipiScan™ IVUS is a new device that combines the novel ability of LipiScan™ to identify lipid core plaque with the established value of intravascular ultrasound (IVUS) to visualize stents and the structural features of coronary plaques.*

**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 diagnosis related groups (DRGs).

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:  
  
*FDA submission is expected December, 2009. Approval is anticipated in the second quarter of 2010.*
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 product will be available immediately after FDA approval.*
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.

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

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*The ICD-9-CM procedure code(s) are 38.23 Intravascular spectroscopy and 00.24 Intravascular imaging of coronary vessels.*

- 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#TopOfPage](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 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](http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage) for more information.)

*An application for <sup>TM</sup> IVUS has not been filed.*

### **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 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/10FR/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1227460&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.

*The average standardized charge per case is \$15,960.*

9. 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?

*The total estimated cost per case for the technology is \$3,000.*

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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*The cost of the technology equals the cost of the single use LipiScan™ IVUS catheter which has a list price of \$3000*

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

*MS-DRGs 246 through 251.*

11. What is the anticipated volume of Medicare cases involving of this technology in FY 2011 (by DRG)?

*Anticipated volume of units is 8,966 divided equally over DRGs 246-251.*

### **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:

*Together the use of both sound and light, found in the LipiScan™ IVUS imaging system, to interrogate the coronary artery produces an improved diagnostic capability.*

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

*Please see the actual application as the articles are too numerous to list here.*

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