



**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 (INIRS)*
2. Manufacturer Name: *InfraReDx, Incorporated*
3. Trade Brand of Technology: *Lipiscan™ Coronary Imaging System*
4. Brief Description of Service or Device: *INIRS can identify lipid core plaque (LCP)
within human arteries*

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:

The device was approved April 25, 2008.

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 was available immediately after FDA clearance. The first sale was in May

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.

The ICD-9-CM Procedure code is 38.23 Intravascular spectroscopy.

(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.

- 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 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 for more information.)

An application was filed for LipiScan™ with CMS in March, 2009 for an outpatient prospective payment system (OPPS) pass-through payment. A CMS letter of denial was received August 27, 2009 citing that the device did not demonstrate a substantial clinical improvement at this time.

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.

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.

The average anticipated standardized charge per case (case weighted) involving this new technology is \$59,704 for DRGs 246 – 251, please see Appendix A.

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

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(ml/kg/hr); **Devices-** breakdown of the cost of all components used in the new technology, clearly showing which components are the “new” ones).

The cost of the LipiScan™ single use catheter is \$2,400 per catheter per patient.

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

The MS-DRGs to which this technology is assigned are 246-251.

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

For FY 2011 the anticipated unit volume is 1,000 divided equally across MS-DRGs 246-251, or 167 in each.

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.

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

LipiScan™ identifies lipid core plaque within coronary arteries providing a chemical analysis to the cardiologist.

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

The use by clinicians of Lipiscan™ to predict and alter treatment involving embolic peri-stenting MIs, to select the length of artery to be stented, and as an aid in selection of lipid-altering therapy, demonstrates that LipiScan™ affects the management of patients.

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

A detailed list of peer-reviewed articles is found in the response to Question 15 in the section on Clinical Improvement Criterion.

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