



**Tracking Form for Applicants for New Technology Add-on Payments under  
the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal  
Year (FY) 2010**

1. Technology Name:

*Intravascular Near Infrared Spectroscopy*

2. Manufacturer Name:

*InfraReDx Inc., 34 Third Avenue, Burlington, MA 01803*

3. Trade Brand of Technology:

*LipiScan™ Coronary Imaging System*

4. Brief Description of Service or Device:

*Intravascular near infrared spectroscopy (INIRS) does have the capability to identify lipid core-containing plaque within human coronary arteries. Consequently, INIRS has the potential ability to serve as “an index of vulnerability”<sup>1</sup> to possible coronary events.*

*This technology holds promise as a modality useful for improving risk stratification of coronary artery disease patients; providing data that will impact provider treatment decisions; and, potentially linking specific coronary artery plaques to subsequent adverse coronary events.*

*Intravascular near infrared spectroscopy (INIRS) is a technology used during an invasive coronary angiography to interrogate “plaques of interest” that results in the categorization of coronary plaque composition. Using an algorithm to analyze obtained spectral signals, a “chemogram” is created detailing the chemical composition (i.e., lipid core) of the target plaque. In addition, the spectral signals produce a Lipid Core Burden Index, which is a measure of the total amount of lipid core- containing plaques of interest in the coronary artery.*

---

<sup>1</sup> Caplan JD, Waxman S, et.al., Near-Infrared Spectroscopy for the Detection of Vulnerable Coronary Artery Plaques. J Am Coll Cardiol. 2006 Apr; Vol. 47 (8) Suppl C:92-6.

**(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)).**

**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 diagnosis related groups (DRGs).

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

*Date of FDA Clearance: 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 on the market immediately after FDA clearance (April 2008).*

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 38.23 (Intravascular Spectroscopy) was recently awarded and is effective October 1, 2008 [Announced in the Federal Register. Vol. 73, No. 84, April 30, 2008. (Proposed Rule). p. 23580 and 23846]*

- 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.

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

*Not applicable. This procedure is performed on an inpatient basis.*

(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)).

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

## **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/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage).

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 anticipated average standardized charge per case involving this new procedure ranges from: \$41,203 to \$70,724 depending on the MS-DRG assignment. Assuming INIRS cases are evenly distributed across the six MS-DRGs, the estimated MS-DRG case-weighted standardized charge is \$55,354. This is higher than the MS-DRG case-weighted CMS charge threshold amount of \$53,631.*

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? 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).

*Please see the full application for more detailed cost information. Details of this information are proprietary and confidential.*

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

*Intravascular Near Infrared Spectroscopy (INIRS) is performed in patients undergoing invasive coronary angiography. Under the Medicare MS-DRG system, such patients may be classified to one of six possible MS-DRG groups. These MS-DRGs are listed below.*

- *MS-DRG #246: Percutaneous cardiovascular procedure with drug eluting stent w/MCC or 4+ vessels/stents*
- *MS-DRG #247: Percutaneous cardiovascular procedure with drug eluting stent w/o MCC*

(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)--).

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

- *MS-DRG #248: Percutaneous cardiovascular procedure with non-drug eluting stent w/MCC or 4+ vessels/stents*
- *MS-DRG #249: Percutaneous cardiovascular procedure with non-drug eluting stent w/o MCC*
- *MS-DRG #250: Percutaneous cardiovascular procedure without coronary artery stent w/MCC*
- *MS-DRG #251: Percutaneous cardiovascular procedure without coronary artery procedure w/o MCC*

11. What is the anticipated volume of Medicare cases involving of this technology in FY 2010 (by DRG)?

*INIRS is an emerging technology that in the 6 months post FDA clearance has been adopted in 6 hospitals and used for clinical purposes in over 85 patients (this is in addition to the 89 patients enrolled in the pivotal study in centers located throughout the United States). Additional hospitals have expressed strong interest in utilization of the technology. On the basis of this experience it is projected that the procedure will be performed in over 35,000 cases by 2010.*

### **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:

*Requirement #1: Detection of a condition that is not currently detectable.*

*It is well-recognized that the primary diagnostic methods used to detect and manage coronary artery disease, the leading cause of death in the US and root cause of massive Medicare expenditures, do not provide adequate information about the composition of atherosclerotic plaques. Perfusion imaging and coronary angiography provide information about the lumen, but not the wall. Intravascular ultrasound (IVUS) can provide information about plaque volume, but it is not FDA approved for detection of lipid core plaques. OCT, which is not approved for use in the U.S., depends upon dropout of signal for detection of lipid, and cannot be used if blood is in the field of view.*

(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)).

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

*The FDA clearance of near-infrared spectroscopy obtained by InfraReDx in April 2008 was accompanied by an important statement by Dr. Daniel Schulz, Director of the Center for Devices and Radiological Health, that directly addresses Requirement #1.*

*The INIRS system 510(k) clearance was granted “for the detection of lipid core containing plaques of interest and for the assessment of coronary artery lipid core burden.” Dr. Schulz stated in an FDA Press Release that:*

*“This is the first device that can help assess the chemical make-up of coronary artery plaques and help doctors identify those of particular concern.”*

*Requirement #2: The device must permit the clinician to detect a condition earlier than is possible with currently available devices*

*It is extensively documented and widely accepted that most coronary events are caused by plaques that did not produce significant narrowing prior to causing the acute event. Prior to the availability of INIRS, it was not possible to find the lipid core plaques that are strongly associated with causation of acute coronary events. The use of INIRS permits the earlier detection of lipid core plaques in the coronary arteries than is possible with current methods.*

*Requirement #3: Use of the device to make a diagnosis affects the management of the patient.*

*Since FDA approval in April 2008, physicians have reported changes in therapy based on INIRS findings in approximately one fourth of patients.*

*The most common use of INIRS results has been for selection of the length of artery to be stented. In some cases a longer stent has been used when there is a lipid core plaque adjacent to the area that is being stented for the presence of a flow-limiting stenosis. The practice of avoiding placement of the end of a stent in a lipid core plaque is supported by autopsy studies showing late stent thrombosis occurring at such a site.*

*In other cases INIRS has been used to select a shorter length of artery to be stented. This has occurred when there is a tight luminal narrowing tapering to lesser narrowing. Demonstration of the absence of a lipid core plaque in the less narrowed lumen has permitted stenting of a shorter length of artery.*

*Other uses include assistance in selecting the appropriate target for lipid altering therapy, for management of bifurcation lesions, and as an additional parameter to consider in the selection of medical, stenting or coronary artery by-pass grafting.*

**(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)--).**

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

*For a complete discussion of the substantial clinical improvement attributable to the use of INIRS, please see the full application.*

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

*Gardner CM, Tan H, et.al. Detection of Lipid Core Coronary Plaques in Autopsy Specimens With a Novel Catheter-Based Near-Infrared Spectroscopy System. JACC: Cardiovascular Imaging. 2008 Sept; Vol.1 (5): 638-647.*

*Young J. Detection of Vulnerable Coronary Artery Plaques (Editorial Comment). JACC: Cardiovascular Imaging. 2008 Sept; Vol.1 (5): 649-651.*

*Maini B. Clinical Coronary Chemograms and Lipid Core Containing Coronary Plaques (Letter to the Editor). JACC: Cardiovascular Imaging. 2008 Sept; Vol.1 (5): 689-690.*

*Moreno PR, Lodder RA, et.al.,. Detection of Lipid Pool, Thin Fibrous Cap, and Inflammatory Cells in Human Aortic Atherosclerotic Plaques by Near-Infrared Spectroscopy. Circulation. 2002 Feb; 105: 923-927.*

*Muller JE, Tawakol A, et.al.,. New Opportunities for Identification and Reduction of Coronary Risk: Treatment of Vulnerable Patients, Arteries, and Plaques. J. Am. Coll. Cardiol. 2006 Apr; Vol. 47 (8) Suppl C: 2-6.*

*Caplan JD, Waxman S, et.al., Near-Infrared Spectroscopy for the Detection of Vulnerable Coronary Artery Plaques. J Am Coll Cardiol. 2006 Apr; Vol. 47 (8) Suppl C:92-6.*

*Waxman S, Ishibashi F, et.al, Detection and Treatment of Vulnerable Plaques and Vulnerable Patients- Novel Approaches to Prevention of Coronary Events. Circulation. 2006 Nov; 114: 2390-2411.*

*Waxman S, Dixon SR, et.al.,. First-In-Human Experience with a Catheter-Based Near-Infrared Spectroscopy System for Detection of Lipid Core Coronary Plaques: Results of the SPECTroscopic Assessment of Coronary Lipid (SPECTACL) Multicenter Study. Submitted for publication.*

*Bosch, JL, Beinfeld, MT, Muller JE, et al. A Cost-Effectiveness Analysis of a Hypothetical Catheter-Based Strategy for the Detection and Treatment of Vulnerable Coronary Plaques with Drug-Eluting Stents. Journal of Interventional Cardiology. 2005 Vol 18(5):339-349.*

**(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)--.**

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