



**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: Auto Laser Interstitial Thermal Therapy (AutoLITT™) System
2. Manufacturer Name: Monteris Medical
3. Trade Brand of Technology: AutoLITT System
4. Brief Description of Service or Device: The AutoLITT™ System is a minimally-invasive, MRI-guided, MRI-thermometry method for delivering focused laser-induced interstitial thermal therapy (f-LITT). The technology enables a physician to selectively and precisely heat brain tumors to cause coagulative tissue death throughout the tumor. The procedure involves inserting a thin (3mm) side-firing laser probe through a small burr hole in the skull into a tumor, then firing the laser to heat the tumor from the inside out to the tumor boundary. Conducted with the patient in a standard MRI, the neurosurgeon visualizes and controls thermal energy deposition and resultant tumor cell death in real-time using the Company's proprietary thermal imaging software and treatment mechanisms.

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 Clearance received May 2009
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 AutoLITT system will be available in December 2009 following suggested and required updates to the technology.
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?

Yes

- 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 new codes include the following:

New category 17.6 MRI-guided laser interstitial thermal therapy (LITT)
Focused Laser Interstitial Thermal Therapy LITT (f-LITT)
under MRI guidance

New code 17.61 MRI-guided laser interstitial thermal therapy (LITT) of
lesion or tissue of brain

New code 17.62 MRI-guided laser interstitial thermal therapy (LITT) of
lesion or tissue of head and neck

- 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. N/A

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.) As of yet, no application has been submitted. However, as the AutoLITT technology develops, the intention is to initiate trials evaluating the potential for outpatient procedures. When this occurs, the intention would be to submit for a transitional pass through payment code.

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.

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 the AutoLITT technology is: **\$96,397**

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). See attached spreadsheet Monteris AutoLITT new tech add on payment
10. List the diagnosis-related groups (DRGs) to which cases involving this new technology will most likely be assigned. DRGs 25-27
11. What is the anticipated volume of Medicare cases involving of this technology in FY 2010 (by DRG)? We anticipate that all of the patients treated with AutoLITT in CY 2010 will be patients that are currently untreatable/refractory to other therapies (i.e. difficult to reach with surgical resection) and will fall under DRG 25 with Major Complications and Comorbidities. Volume of Medicare cases is expected to be approximately 30% of all cases; or approximately 70 cases out of 234 total procedures.

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:

A significant number of brain tumor patients lack effective treatment, even with the advances of surgery, radiotherapy, and chemotherapies. For example, approximately 20-30% of newly diagnosed high-grade glioma (glioblastoma) patients are not amenable to surgical resection, have tumors too large for SRS, and even with the advances in chemotherapy (Stupp regimen), still have a dismal prognosis. Most (company estimate of 75-90%) of these patients are accessible with AutoLITT. Current treatment methodologies used for other brain tumors have similar limitations. Therefore, AutoLITT improves the current clinical circumstances by providing an option for those patients that are underserved by current methodologies. Additionally, the minimally invasive nature of the AutoLITT procedure allows for quicker recoveries and improved quality-of-life results, and in general does not preclude use of subsequent other methods of treatment in the event of recurrence or incomplete treatment. Several non-AutoLITT clinical trials have demonstrated that non-focused LITT (and more recently, the use of LITT plus MRI) have improved survival, quality of life and recovery in patients with advanced glioblastoma multiforme tumors and advanced metastatic brain tumors that cannot be effectively treated with surgery, radiosurgery, radiation, chemotherapy or any currently available clinical procedure.

In a number of these patients, non-focused LITT was the treatment of last resort, due to either the unresponsiveness or inability of these therapies to treat the brain tumor (due to tumor location, type, size, etc.).^{1,2}

Improved clinical outcomes using non-focused LITT have included reduced recovery time^{3,4,5,6,7} and a reduced rate of complications (i.e. infection, brain edema)^{8,9,10}. These criteria as described in the Federal Register¹¹ (i.e. treatment option for disease refractory to other treatments, clinical outcomes) meet the new technology requirement of substantial clinical improvement.

It is anticipated that the Monteris AutoLITT would represent a substantial clinical improvement over existing standards of care for a number of reasons and should build upon less sophisticated, non-focused LITT therapies. These clinical improvements include: a less invasive method of tumor ablation, potentially leading to lower complication rates post procedure (infection, edema); an ability to employ multiple interventions over shorter periods of time and an ability to be used as a treatment of last resort (as noted above other therapies such as radiosurgery are limited due to radiation dosing and craniotomy is limited to 1-2 procedures); an ability to be used in hard to reach brain tumors (thus again AutoLITT may be used as a treatment of last resort); and a shorter recovery time (the possibility for same day surgery – this has been demonstrated above with non-focused LITT).

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

A peer reviewed article on the use of the Monteris AutoLITT in Glioblastoma patients refractory to other available therapies will be published early next year.

¹ Von Templehoff, W et al. (2002). LITT (Laser Induced Interstitial Thermotherapy) of Benign and Malignant Gliomas in the OPEN MR (0.5 Tesla, GE Signa SP). *Med Laser Appl.*;17:170-178.

² Carpentier, A. et al (2008). Real-Time Magnetic Resonance-Guided Laser Thermal Therapy for Focal Metastatic Brain Tumors. *Neurosurgery*;63:ONS21-ONS29.

³ Reimer, P et al. (1998). MR-monitored LITT as a palliative concept in patients with high grade gliomas: preliminary clinical experience. *Jrl. Mag Reson Imaging*;8:240-244.

⁴ Kowalik, K et al. (2000). Initial assessment of costs and benefits of MRI-guided brain tumor resection. *Eur. Radiol*;10:S366-367 [Suppl. 3]

⁵ Hall, WA et al. (2002). Costs and Benefits of Intraoperative MR-Guided Brain Tumor Resection. *Acta Neurochir*;85:137-142. [Suppl]

⁶ Schwarzmeier, HJ et al. (2006). MR-guided laser-induced interstitial thermotherapy of recurrent glioblastoma multiforme: Preliminary results in 16 patients. *Eur Jrl. Radiology*,59:208-215.

⁷ Carpentier, A. et al. (2008). Real-Time Magnetic Resonance Guided Laser Thermal Therapy for Focal Metastatic Brain Tumors. *Neurosurgery*;63:ONS21-ONS29 [ONS Suppl 1]

⁸ Reimer, P et al. (1998). MR-monitored LITT as a palliative concept in patients with high grade gliomas: preliminary clinical experience. *Jrl. Mag Reson Imaging*;8:240-244.

⁹ Paleologos, TS et al. (2000). Clinical Utility and Cost-Effectiveness of Interactive Image Guided Craniotomy: Clinical Comparison between Conventional and Image Guided Meningioma Surgery. *Neurosurgery*;47:40-48

¹⁰ Mehrkens, J. et al. (2005). Interstitial Photodynamic Therapy of Recurrent Malignant Gliomas Using 5-Aminolevulinic Acid (5-ALA). *Neuro-Oncology*;Abstract #110; Abstracts from the World Federation of Neuro-Oncology Second Quadrennial Meeting and the Sixth Meeting of the European Association for Neuro-Oncology. May 5-8, 2005

¹¹ Federal Register, 66 CFR 46914-15, September 7, 2001